**Submitter :** **Dr. Malcolm Moore** **Date: 01/24/2005**

**Organization :** **Eye Center of Central Georgia**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

I am protesting the reimbursement of Rocephin, J0696. Our cost is $12.20 per 250mg. The reimbursement after Jan. 1, 2005 is $6.57 per 250mg, 54% of what we pay for the medication. We will not be able to provide this medication to our patients with this reimbursement.
Also, butorphanol, J0595, we pay $3.68 per 1G, the reimbursement now is $1.82 per gram.
Please let me know where we can purchase these drugs at this price, or adjust your reimbursement to a fair level.

**Submitter :** **Dr. Jorge Ferrer** **Date: 03/29/2005**

**Organization :** **Veterans Health Administration**

**Category :** **Federal Government**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-2-Attach-1.DOC

| Item # | Page / Section | Comments | Degree of Concern | Review Status/Dispensation |
|---|---|---|---|---|
| | *Citation of page or section* | *List the topic/issue/comment with each residing on a separate line.* | *Major / Minor / Comment / Question* | *Final dispensation after review by requestor and discussion by team.* |
| 1. | Page 6261, I. Background, G. Electronic Prescription Drug Program | Is the Ordering Provider expected to participate in the adjudication process involving eligibility for patients they are prescribing for? What is the Ordering Provider's implied liability of the eligibility function during e-prescribing? | Question | |
| 2. | Page 6256, I. Background, A. Statutory Basis | Would the VHA have the legislative authority to enroll and serve the needs of Part D eligible individuals? Would this be in conflict with already existing Federal Register rules regarding Medicare billing for Medicare beneficiaries? | Question | |
| 3. | None, General Question | How would VA tortiously liable billing rates factor in to the process? HIPAA ET&CS currently define the acceptable formats, but would these reimbursement conditions impact front-end order entry processes via e-prescribing? | Question | |
| 4. | Page 6261, I. Background, G. Electronic Prescription Drug Program | The standard as described within the NPRM indicates an NPI is not required. For the anticipated Final Rule, what are the implications of an NPI if the HIPAA NPI Rule is approved? | Question | |

**Submitter :** **Dr. Stuart Levine** **Date: 03/29/2005**

**Organization :** **Institute for Safe Medication Practices**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-0011-P-3-Attach-1.DOC

**Department of Health and Human Services**
**Centers for Medicare and Medicaid Services (CMS)**
**Offices of Strategic Operations and Regulatory Affairs**

The attachment to this document is not provided because:

1. The document was improperly formatted.
2. The submitter intended to attach more than one document, but not all attachments were received.
3. The document received was a protected file and can not be released to the public.
4. The document is not available electronically at this time. If you like to view any of the documents that are not posted, please contact CMS at 1-800-743-3951 to schedule an appointment.

**Submitter :** **Ms. Lynne Gilbertson** **Date: 03/30/2005**

**Organization :** **NCPDP**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-4-Attach-1.DOC

March 30, 2005

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

***Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments***

Dear Centers for Medicare and Medicaid Services:

The National Council for Prescription Drug Programs (NCPDP) is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

NCPDP is a non-profit ANSI-accredited Standards Development Organization consisting of more than 1,300 members who represent computer companies, drug manufacturers, pharmacy chains and independents, drug wholesalers, insurers, mail order prescription drug companies, pharmaceutical claims processors, physician services organizations, prescription drug providers, software vendors, telecommunication vendors, service organizations, government agencies and other parties interested in electronic standardization within the pharmacy services sector of the health care industry.

**I. Background (F. R. page 6257)**

***A. Statutory Basis***

*Although there is no requirement that providers write prescriptions electronically, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.*

*Section 1860D–4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is "adequate industry experience." Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.*

**NCPDP Response:**

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American National Standards Institute (ANSI) accredited. We are concerned that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

NCPDP supports the naming of standards as draft foundation standards and CMS should encourage adoption on a voluntary basis while these standards go through the ANSI-accredited Standards Development Organization. CMS should not mandate by law these draft foundation standards, until they have been approved. CMS should also not wait until the 2008/2009 dates to adopt these standards.

***2. State Preemption (F.R. page 6259)***

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**NCPDP Response:**

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable, national scheme, physicians and pharmacists will be uncertain as to their obligations with respect to Medicare-covered prescriptions as opposed to other electronic prescriptions which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic e-prescribing software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer (e.g., where multiple coverages exist, which coverage will be the ultimate payer under coordination of benefit rules). "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available or cannot make available because the determination of coverage isn't made until the actual script is filled and the claim is adjudicated. While multiple coverages may present other problems at the point of care as well, such as which formulary and benefit information to show, the rules affecting *how* electronic prescribing is done should not vary based on who the ultimate payer will be.

CMS stated in the preamble to the NPRM "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of State law that will require detailed analysis in all 50 states to determine whether existing State law should be read to mingle with Federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a State requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that State require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?
- Does a Medicare prescription transmitted electronically need to meet State rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?

- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable State forbids such intermediaries?
- Can the physician or pharmacist be disciplined under State law where a prescription is sent electronically according to the Federal rule but it is deficient for State law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer), which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of this ambiguity and confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

We believe a single, national set of regulations for electronic prescribing is in the interest of all parties, including the states. The principal concern of states would not likely be that the Federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that State Boards of Pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the State Boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- Transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- Rules relating to formatting of prescriptions and documentation of the prescriber's intent
- Rules relating to authentication of the prescriber and dispenser
- Rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of Federal and State laws affecting all electronic prescriptions. The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant State law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as Federal standards are adopted for electronic prescriptions, they preempt any contrary State standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above.

Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all State rules on those topics with respect to all electronic prescriptions.

Regarding Long Term Care Settings:

1. Federal, State and insurance payers require paper verification of services rendered including physicians and other health care provider's non-electronic signatures. In order for e-prescribing to work in the LTC setting, the State and Federal survey processes must accept electronic records and signatures.
2. Due to the numerous changes in the level of care for beneficiaries in the nursing facility the e-prescribing model must be available for all payment types not only Medicare Part D. The LTC setting needs a uniform industry standard for e-prescribing.
3. These proposed rules do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different State specific regulations pertaining to the record keeping of controlled substance prescriptions. These State specific regulations are even more unique for the LTC pharmacies and facilities.

**E. Current E-Prescribing Environment (F.R. page 6260)**
**NCPDP Response:**
NCPDP requested clarification of CMS that at this point, long-term care is not addressed in this regulation. NCPDP, at the request of industry participants, has created a new work group for Long Term Care. The scope of this work group is:

> Work Group 14 Long Term Care, in conjunction with the other Work Groups, guides and advises payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation, supports data processing initiatives, and provides design alternatives for standards used within the long term care industry

It is expected that long term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy.

1. In order for e-prescribing to work in the LTC setting the beneficiaries eligibility information must be real time. In the LTC setting, physicians and facility nurses do not know a patient's pharmacy benefits eligibility and coverage. The industry has relied on the LTC pharmacy provider to keep this information. The pharmacy and nursing facility billing offices communicate patient billing status (inpatient or outpatient) which changes by the skilled level of care determined by the patient's medical conditions.
2. Due to the numerous levels of care changes of a beneficiary on a daily basis within a nursing facility, real time eligibility information must be available to the pharmacy and physician to handle the formulary and prior authorization processes within e-prescribing to meet the coordination of benefits (COB) between Medicare Part A, B and D.
3. Medical records for nursing facility patients are located at the nursing facility, not in the physician's office. This causes difficulty when the patients' information is needed from their medical chart. The information gathering process is often left up to the LTC nurses and pharmacists.
4. For e-prescribing to work efficiently in a LTC setting an electronic health record (EHR) is needed. There is an increased need for process adaptations and communication between these healthcare professionals in LTC to assure nursing facilities meet the required Federal regulation to provide prescribed medications to nursing home residents in a "timely manner".

**F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)**

*We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria…*

**NCPDP Response:**

Please see NCPDP response to section " ***I. Background (F. R. page 6257) A. Statutory Basis***".

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**NCPDP Response:**

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing. NCPDP appreciates that HHS is looking to name a minimum standard of NCPDP SCRIPT Version 5.0, but not stifle industry movement to versions above this, as business needs arise. With the suggested naming of NCPDP SCRIPT Standard Version 5.0 in this NPRM, the industry will begin looking at this version, if they are not already supporting it. It is anticipated that industry participants will actually look at later versions of NCPDP SCRIPT Standard and implement these, since the modifications are not major, and then be able to support version 5.0 and above. It is also important to not negatively impact the traction of the current e-prescribing environment by naming a version the industry is not able to support timely. NCPDP SCRIPT Standard Version 5.0 gives the industry the "floor".

It is important to allow the evolution of the industry. The support of a new version takes time as products are developed and rolled out to the industry.

NCPDP has had several discussions about version management methods whereby newer versions of a standard could be adopted and older versions retired in order to balance the needs of stakeholders who are working to expand the capabilities of a given standard versus those who are merely wishing to comply with the minimum necessary standards. We offer the following recommendations for your consideration. NCPDP would welcome the opportunity to meet with HHS and other SDOs to further discuss the issues related to the management of standard versioning under MMA, especially if there are areas that the current Federal rulemaking requirements may be in conflict with the scenarios we describe. (Note, in the context of the recommendations, "HHS" is used. You may determine that CMS is the more appropriate authority for this role.

In addressing version management, NCPDP is attempting to accommodate a diverse set of requirements in order to achieve optimal effectiveness of the technical standards we and other SDOs develop. One overarching philosophy behind our recommendations is that the industry stakeholders collectively offer the best source for knowing the optimal range of capabilities within the industry. Thus, we need a mechanism for advancing the industry as a whole that doesn't force everyone to stay in lock step with each other in order to maintain interoperability. Naming one version of a standard as the only acceptable version for use impedes progress and innovation; requiring simultaneous adoption of newer versions can create disruptive and inefficient transitions that are prone to error rather than a more natural evolutionary process; allowing for newer versions of a standard while still supporting older versions helps to alleviate some of these problems, but has a secondary effect of creating inefficiencies over time as backward compatibility must be maintained to the oldest version in order to retain some level of interoperability.

We note that in other industries where market forces play a greater role than regulatory requirements, there is a relatively organic process by which new versions are introduced and adopted by stakeholders when the perceived advantages of the new version offer a

competitive advantage over maintaining an older version. For example, a large organization using Microsoft Windows® as an operating system may not choose to upgrade to a new version every time it comes out, but would "leapfrog" to save the transition costs and inefficiencies inherent in change. They would also stagger the transition so that some colleagues would be on Windows 2000 and others on XP. But they would also make sure that no one stayed on Windows 98 to avoid problems with backward compatibility and employee inefficiencies.

The strategy we propose attempts to address all these issues while maintaining an open process that allows all stakeholders to voice their opinions during the decision-making process.

In the following example, the adoption of a new version or release of a standard would be independent of the retiring of an older version; they could happen simultaneously, but introducing a new version or release would not automatically force the retiring of an older version or release. Other assumptions of the model we present include the following:

- The timing of version or release development can vary. When there are many advances in the industry around electronic interchange, there may be a need to have a more rapid cycling of the standard; as a standard arena stabilizes, the need to advance to a new version or release will slow. Therefore, we haven't included specific lifecycle timelines in the model, but rather have established dependencies as to what order changes must occur.
- The number of versions or releases that are accepted as "active" standards can change over time. The decision of whether a change to a standard constitutes a "version", "release" or merely a "document revision" is SDO dependent and should not be constrained by the Federal standard version naming process. It would be problematic to require, for example, that every new version go through the Federal approval process in the case where the changes to a version were made for reasons that are not tied to a specific law or regulation (like the introduction of pediatric dosing that would not apply to Medicare Part D). While it is reasonable to assume that there wouldn't be a need for more than four versions to be active at any one time, it would be better to allow the SDO vetting process to determine the best timing for each new version approval or retirement.
- Similarly, a new federally approved version of a standard could be a true "version" (i.e., v7.0 to v8.0) or a "release" (i.e., v7.4 to v7.5). From this point forward, "version" will be assumed to mean either version or release unless stated otherwise.
- The Federally approved versions do not have to be directly sequential. For example, versions 5.0, 5.1, 6.0, 7.0, and 7.1 are approved. The three versions chosen by the industry to have active might be 5.0, 6.0, and 7.1, based on the business requirements.
- HHS would work in cooperation with the SDOs to determine the best timing for advancing and retiring versions of the standard.
- For named transactions/standards, at least two versions would be Federally approved at any given time. The actual number of versions that would be approved at any given time would be determined by through the SDO voting process.
- When a new standard was being adopted for the first time, the most current version would possibly be the only version approved.
- Implementers of the standard would be able to use any version/release in the current valid range of version/releases for their exchanges through networks or trading partners. But implementers of later versions would have to be capable of sending or receiving transactions in the older approved. This would allow

implementers to take advantage of technical advances within a standard when exchanging information with other advanced implementers, but would not force those implementers using older, but still valid, version/releases to upgrade before they are ready.

- Implementers will likely "skip" through the versions (i.e., use Windows 98 for a few years, but skip over Windows 2000 when Windows XP comes out.).
- HHS would establish an alert mechanism (an email listserv, for example) that interested stakeholders could subscribe to with respect to a specific standard so that they would be aware of upcoming open forums, introductions of new versions and plans to retire old versions. HHS could choose to request that individual SDOs maintain this process.

An NPRM on versioning methodology that is separate from this current e-prescribing NPRM may be required be for adopting this or a similar methodology. But the overall goal of this methodology would be to avoid the formal rulemaking process when introducing new versions of a standard while still allowing for a fully open process.

Version Management Process for Advancing a New Version:

1. The SDO works through its normal consensus process to advance a new version of a standard.
2. The SDO achieves internal consensus (workgroup level) for a new version and votes whether this version should be presented to HHS as an MMA standard.
3. The SDO prepares the version for ballot and in the case of an affirmative vote, the SDO presents the incremental changes in the standard to NCVHS to allow for public comment and invites interested stakeholders to participate in the ballot. This process takes place before or in parallel with the SDO balloting process so that no time is lost. (Alternatively, this open hearing could be an SDO- or HHS-managed process via publicly announced teleconference.)
4. NCVHS sends a letter of notification to HHS within 15 days of the hearing with its recommendation to accept the standard when balloted successfully and notes any substantive comments received during the hearing.
5. The SDO ballots the standard.
6. The SDO reconciles negative votes. (As the SDOs are ANSI-accredited, they must ensure that all stakeholders have adequate opportunity to voice opposition and that due process was followed.)
7. Upon successful resolution of ballot, the SDO submits to HHS (and copies NCVHS on) a request for this new version to be adopted, with an implementation timeframe.
8. HHS announces the new version in Federal Register. The implementation date would be the date of publication as the adoption of this latest version would be voluntary. The version(s) that have been announced previously are still valid for use until retired.

Version Management Process for Retiring an Old Version:

1. The SDO works through its normal consensus process to discuss the retirement of an older version of the standard. At least two newer versions must have been approved through the process outlined above. Conditions for retirement may include:
    a. Industry consensus that maintaining active use of an older version would no longer be cost effective or would not support what are considered to be current best practices
    b. Industry consensus that the older version is no longer in wide-spread use

2. The SDO achieves internal consensus (at the workgroup level) that a version should be retired and prepares to put this recommendation to an SDO-wide vote.
3. While preparing for the full-SDO vote, the SDO presents their proposal to retire the version to NCVHS to allow for public comment and invites interested stakeholders to participate in the voting.
4. NCVHS sends a letter of notification to HHS within 15 days of the hearing with its recommendation to retire the version/release of the standard should the SDO ballot be successful and notes any substantive comments received from the hearing.
5. The SDO conducts an SDO-wide vote on retiring the version.
6. Upon passage, the SDO submits to HHS (and copies NCVHS on) a request to retire the version, with an implementation timeframe that does not cause undue burden on implementers.
7. Upon review, HHS announces retirement of the version in the Federal Register.

NCPDP suggests this process be followed for the NCPDP standards (and potentially other standards) named as part of the MMA or named in the future. The process would be invoked when the industry requests a new version of any of the NCPDP standards named as part of the MMA (excluding standards already named in HIPAA), or a new standard to be named. NCPDP also suggests that HHS consider using this process for advancing HIPAA named standards. The timings suggested above – such as the NCVHS reporting process – would have to be reviewed for feasibility and resource requirements. It may be better, for example, that NCVHS serve as the public announcement vehicle, but that the actual open forum is held by HHS or by the SDO itself.

An alternative step might be to schedule a regular, predictable cycle for holding hearings on submitting or retiring versions of a standard, for example. We welcome the opportunity to work with HHS to hone these concepts further so that they meet the needs of all stakeholders, comply with Federal law, and ultimately result in advancing patient care.

**G. Electronic Prescription Drug Program (F.R. page 6261)**
**NCPDP Response:**
Within the proposed rules the impact on the Nursing Facility, LTC Pharmacies or Physicians serving Nursing Facilities is not addressed, as related to the MMA.

1. In the LTC setting there is a need to develop technology for a three-way communication between off site physicians, nursing facility medical record and LTC provider pharmacies. Have some incentives for nursing facility staff for training of high turnover nursing staff and access to computers for data entry. Nursing facilities have very few computer workstations and are still using a very manual charting process.
2. Prescription Drug Plans (PDP), LTC pharmacies, physicians and nursing facilities may incur additional costs different than the ambulatory setting since a more complex process of a three-way communication must be developed for an e-prescribing model to be successful in the LTC setting.
3. If the LTC setting is excluded from an e-prescribing process, this could add a strain to the physicians who have ambulatory and nursing facility patients.

**(F.R. page 6263)**
*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance*

*dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**NCPDP Response:**

The NCPDP Provider ID is the current de facto standard pharmacy identifier used for both the NCPDP Telecommunication Standard Version 5.1 and the NCPDP SCRIPT Standard. Both of these standards will support the use of the NPI to identify the dispenser. Industry is only now analyzing the system changes necessary for industry to begin using the NPI for HIPAA named transactions. No analysis has been done to assess the impact of using the NPI as a standard identifier for pharmacies in electronic prescribing. It is not likely that pharmacies will realize any positive financial impact of making this change and doing so may slow voluntary adoption. Therefore, NCPDP believes since the use of the NPI for this purpose has not been proven, its use should not be accelerated.

The NPI and the NPPES were not designed with electronic prescribing in mind. For example, an NPI may be assigned to organizations and subparts, but organizations cannot prescribe, only people. Additionally, some prescribers are not currently required to obtain an NPI under the HIPAA regulations. If the NPI is named as a standard for electronic prescribing, it is imperative that all prescribers including those not sending or receiving HIPAA transactions be required to obtain an NPI. Allowing an alternative identifier for prescribers that do not need to obtain an NPI under HIPAA would only result in the need to support multiple identifiers, which is contrary to administrative simplification.

Because the NPI and the NPPES were not designed with electronic prescribing in mind, industry will need to devise other methods of determining routing instructions for prescribers with multiple practice addresses if used. Industry will also need to determine whether a given NPI is that of a prescriber or an organization. The use of proprietary databases mapping the NPI to routing information and providing other information needed for authentication will be critical to successful messaging. These mechanisms are not currently in place as the numbers currently used by industry support multiple practice addresses and only enumerate prescribers.

The NPI is not meant to replace the DEA number or the Taxpayer Identifying Number that were established for purposes other than the purpose of the NPI and careful consideration must be given to using the NPI for this new purpose.

NCPDP suggests that (1) both the NPI and the NCPDP HCIdea® prescriber identifier be utilized in pilot programs to determine the applicability of each of the identifiers, that (2) a standard identifier for prescribers be named only after there is adequate industry experience in the use of the named identifier and that if the NPI is the named standard, (3) acceptable business practices are available for distribution of the NPI file to the industry. Until that time, we suggest the e-prescribing industry continue to use existing identifiers that support business purposes that the NPI currently does not support, such as transaction routing to specific locations.

**(F.R. page 6263)**

*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

**NCPDP Response:**

There is adequate industry experience in using the NCPDP Provider Identifier Number for identifying dispensers. NCPDP recommends that this identifier should be supported

until such time as the NPI has proven to be a successful identifier for electronic prescribing. To require the use of the NPI to identify dispensers for electronic prescribing prior to successful pilot testing would be a disservice to e-prescribing and may slow voluntary adoption.

In identifying prescribers, NCPDP suggests that both the NPI and NCPDP HCIdea® be included in pilot tests and that the standard identifier best suited for electronic prescribing is selected for that purpose. If not selected as the standard prescriber identifier for e-prescribing, the HCIdea® Database may prove to be useful as a bridge for dispensers between the DEA, the NPI, and other identifiers currently used for prescriber identification. This bridge or cross walk between the NCPDP HCId®, the NPI**,** the DEA and other possible identifiers such as State license number and UPIN number may support healthcare organizations in populating their prescriber files with the proper NPI for each prescriber, linking one prescriber to multiple practice addresses and routing SCRIPT messages to the proper practice address (which can not be done with the NPI alone).

**Formulary And Medication History Standards (F.R. page 6263)**
*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*
**NCPDP Response:**
Testimony to NCVHS showed industry experience. Medication History Standard has been brought forth to NCPDP and is being balloted. The Formulary and Benefit Standard has been brought forth to NCPDP and upon approval, will be taken to ballot. As with any standard, if business needs are brought forward, they will be discussed and taken through the approval process.

**(F.R. page 6263)**
*We propose the following critical characteristics for formulary and benefit data standards:*
**NCPDP Response:**
See above.
**(F.R. page 6263)**
*We propose the following critical characteristics for medication history standards:*
**NCPDP Response:**
See above.

**Drug Information (F.R. Page 6264)**
*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*
**NCPDP Response:**
Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. Access to referential electronic drug information should be part of the overall physician practice management system and access to this type of information should not hinder the exchange of e-prescribing data. The availability and type of drug information made available to the prescriber should be determined by the prescriber's practice setting and individual needs.

**H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)**
*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other*

*necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

*• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

**NCPDP Response:**

NCPDP supports these foundation standards. NCPDP recommends the minimum standard be the version named and that other higher versions, if backward compatible, are also acceptable, except where HIPAA supercedes this Final Rule. Please see NCPDP's response at section **"*F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)*"**, where it is recommended that consideration for changes be given to HIPAA-named transactions**.**

The completed NCVHS Standards Worksheet indicated several gaps in the ASC X12N 270/271 Eligibility Inquiry and Response Standard. The near term solution proposed

> *"Where there are gaps in the information that needs to be transmitted in the 271 response (such as the need for formulary or benefit identifiers) the transaction does have a free form message segment that could outline the details that cannot currently be codified."*

Until the long-term solution is adopted under HIPAA, NCPDP requests the ASC X12N 270/271 Workgroup publish a document that outlines the details on how to use the free form message. The benefit of the document is a consistent implementation of the free form message.

**(F.R. Page 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**NCPDP Response:**

NCPDP can see no benefit to impeding the momentum driving the adoption of e-prescribing nor the development and implementation of standards for e-prescribing. E-prescribing and EHRs can exist both in an integrative and independent fashion. EHR is very broad and may be implemented in different timeframes and may be driven by different business and clinical needs. E-prescribing is available today and is being used in many clinical settings. As functionality is available, it should be incorporated into the whole continuum of care; but do not postpone implementation of the parts that are available today.

## II. Provisions of the Proposed Regulation (F.R. Page 6264)

### B. Proposed Definitions (F.R. Page 6265)

- *Dispenser means a person, or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.*

- *Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.*
- *E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.*
- *Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.*
- *Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.*
- *Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information or a Part D eligible individual enrolled in a Part D plan.*

**NCPDP Response:**

NCPDP supports the definition of e-prescribing. E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information.

Non-EDI Messages (e.g., Faxes or Emails)
Messages that leave or enter the system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions.

NCPDP supports the definition of electronic media.

NCPDP recommends the definition of Prescriber be expanded to authorized prescribers of drugs for human or animal use.

**C. Proposed Requirements for Part D Plans (F.R. Page 6265)**
**(F.R. Page 6265)**

*We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.*

**NCPDP Response:**

NCPDP agrees with the recommendations from NCVHS that when transmitting information outside the enterprise, the named standards should be used (NCPDP SCRIPT, etc). NCPDP does not believe that the standards should be required for e-prescribing transactions within the enterprise. We do not see an advantage to require this within the same time period as outside of the enterprise.

**E. Proposed Standards (F.R. Page 6265)**

*We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

**NCPDP Response:**

NCPDP supports this approach. NCPDP supports trading partners using these transactions, especially in the 2006 pilots. We have completed the creation of additional documentation clarifying the proper use these transactions. These additions will be included in the next NCPDP SCRIPT Standard Implementation Guide.

**(F.R. Page 6265)**

*We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:*

*• New prescription transaction*
*• Prescription refill request and response transactions*

*• Prescription change request and response transactions*
*• Cancel prescription request and response transactions*
*• The following ancillary messaging and administrative transactions:*
*+Get message transaction*
*+Status response transaction*
*+Error response transaction*
*+Verification transaction*
*+Password change transaction*

**NCPDP Response:**
NCPDP supports this list.

**(F.R. Page 6266)**
*We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.*

**NCPDP Response:**
There is a difference between "adopt" and "require". NCPDP recommends CMS adopt these different transactions, but not require them unless the business need or the technology solution is demonstrated. For example, if a provider is connected via the internet/leased line/frame relay, they may not need to support GETMSG mailboxing functions. Why require it when they do not need it?

There is industry experience with STATUS and ERROR. The STATUS and ERROR messages are used today, and these are part of the "real-time" request and response environment of transaction processing. The STATUS and ERROR messages perform transactional functionality; this is different than the housekeeping transactions.

The GETMSG and PASCHG are housekeeping functions. There is adequate industry experience with GETMSG and PASCHG, for those entities needing the functionality.

GETMSG and PASCHG are in a sense internal messages: they flow only between a provider and his mailboxing service (e.g., aggregator), not from one provider to another. Thus, an aggregator may never see GETMSGs from prescribers or an aggregator may never see GETMSGs from pharmacies (depending on the relationship of the technology between the aggregator and the provider). In some instances where a partner does not have a static IP address and "listening capabilities" the GETMSG and PASCHG are being used.

VERIFY is a return receipt function. VERIFY is only used when someone needs it (much like requesting return receipt at USPS; not all mail needs return receipt). The VERIFY message may be used by the end users and sometimes by network partners. There is industry experience using VERIFY, although it should not be a required function as it is not a business function transaction, but rather a special case transaction.

**2. Eligibility (F.R. Page 6266)**
*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

**NCPDP Response:**

The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

A clarification. The NCPDP Telecommunication Standard is EDI and was named in HIPAA. It does not adhere to EDIFACT or ASC standards. The NCPDP Telecommunication Standard was named in HIPAA for eligibility between pharmacies and payers. The pharmacy industry will be using the Telecommunication Standard for eligibility checking under MMA, especially in determining coordination of benefits information.

E-prescribing should not be hindered by the length of time that modifications are adopted in HIPAA named transactions.

**(F.R. Page 6267)**

*If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the* ***Federal Register*** *of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

**NCPDP Response:**

Please see NCPDP's response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

**(F.R. Page 6267)**

*We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

**NCPDP Response:**

Please see NCPDP's response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

**IV. Regulatory Impact Analysis (F.R. Page 6268)**

*We invite public comment on our expectations for prescriber participation.*

**NCPDP Response:**

Please see NCPDP's response at section " ***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)**

*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**NCPDP Response:**

The NPI is not in use today and the impact on pharmacies of adopting the NPI as an identifier for the electronic Prescriber may not be positive. Prescribers are defined as people and NPIs are to be assigned to places as well as people. The NPPES was not designed with e-prescribing in mind. Some Prescribers do not submit HIPAA transactions and will not have NPIs. The impact could well be negative if the NPI is not piloted and electronic prescriptions are received by pharmacies from places.

It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new standards and

new versions of the standards must be predictable and timely (i.e., sensitive to current industry adoption capabilities) so as not to negatively impact the movement of the industry as it addresses new business functions and needs.

**E. Impact on Patients (F.R. Page 6271)**
**NCPDP Response:**
We agree that the adoption of electronic prescribing will have a net positive impact on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance.

**G. Impact on Small Businesses (F.R. Page 6271)**
*Accordingly, we conclude that this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. We welcome comments on this conclusion and additional information on the small business effects of this proposed rule.*
**NCPDP Response:**
Participants of NCPDP noted that small businesses, independent pharmacies, small prescriber environments are already using SCRIPT. We are not aware of other studies and agree that more studies will need to be funded to assess and evaluate the overall impact on each of the participant entities. These would be valuable to the industry as a whole.

**H. Effects on States and Federalism Statement (F.R. Page 6272)**
**NCPDP Response:**
Please see NCPDP's response at section "***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**I. Conclusions and Alternatives Considered (F.R. Page 6272)**
*We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*
**NCPDP Response:**
NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard. Please see NCPDP's comments in Section *"G. Electronic Prescription Drug Program (F.R. page 6261)."* NCPDP believes that the NCPDP HCIdea prescriber identifier, which enumerates prescribers and not places, should be piloted as an alternative to the NPI for e-prescribing applications.

**(F.R. Page 6273)**
*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*
**NCPDP Response:**
NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard, and the Formulary and Benefit Standard.

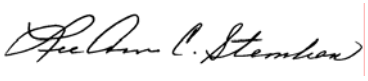
**PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**
NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard.

**Conclusion**
NCPDP supports phasing in electronic prescribing in a way that leverages industry momentum and builds on the considerable experience and success the industry has had to date.

To encourage the voluntary adoption of electronic prescribing by prescribers and dispensers and facilitate consistent implementation by payers, technology providers, and intermediaries, NCPDP supports a single, national, comprehensive set of regulations applicable to all electronic prescriptions, not just electronic prescriptions for Part D enrollees. Otherwise, the Part D program becomes yet another set of regulations that must be reconciled by each participating entity with the current 50-state scheme for regulating electronic prescribing. NCPDP believes adding complexity to an already-challenging regulatory environment will hinder voluntary adoption rather than facilitate it—particularly since compliance would require definitive coverage information at the point of prescribing.

NCPDP stands ready to assist CMS in the continued success of electronic prescribing. NCPDP members and staff are committed to the actions cited in the MMA, have brought forth standards forward where available or needed, and facilitated industry task groups dedicated to the implementation of e-prescribing.

Sincerely,



Lee Ann C. Stember
President
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

cc: NCPDP Board of Trustees

**Submitter :** **Ms. Patricia Wilson** **Date: 03/31/2005**

**Organization :** **Associates & Wilson**

**Category :** **Individual**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-0011-P-5-Attach-1.DOC

Associates & Wilson
1084 East Lancaster Avenue
Rosemont, PA 19010
www.associatesandwilson.com
p.wilson@associatesandwilson.com

March 31, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P.
Submitted to http://www.cms.hhs.gov/regulations/ecomments
Re: CMS-0011-P. Comments on E-Prescribing Proposed Rule 70 Fed. Reg. 6256 (Feb. 4, 2005)

Dear Sir or Madam:

This letter constitutes our comments on the E-Prescribing proposed rule cited above. Comments are submitted on "Provisions" specifically recommending that proposed 423.159 be expanded to incorporate a new paragraph (b) requiring that all new prescriptions contain the diagnosis (or diagnoses), and that the definition of "prescription-related information" in proposed 423.159(b) include the diagnosis. This letter is being submitted electronically to www.cms.hhs.gov/regulations/ecomments as a Microsoft Word document. The submission was made before the deadline of 5PM on April 5, 2005.

We propose adding the requirement of a ***diagnosis (Dx) on the prescription (Rx)*** to the e-prescribing rules. We call it *Dx on Rx*. Requiring a diagnosis on the prescription:

1. Supports many of the Medicare electronic prescription drug program requirements and in some cases is necessary to achieve the program requirement.
2. Complies with HIPPA.
3. Is supported by adequate industry experience and therefore would not require pilot testing.
4. Supports and is consistent with MMA cost control and quality improvement requirements.

**1. *Dx on Rx* supports other electronic prescription drug program requirements**

The Act requires an electronic prescription drug program to provide for the electronic transmittal of certain information to the prescribing health care professional and to the dispensing pharmacy and pharmacist. The following statute-required information would be greatly facilitated if the diagnosis was on the prescription:

- **Information on eligibility and benefits** (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) is required by the statute. *Dx on Rx* has the benefit of helping to determine eligibility for prescription plan coverage. Some prescription drugs have multiple uses. Some of those uses are eligible for coverage under Medicare and some are not. Without knowing the diagnosis, plans and pharmacy benefit programs have a limited ability to efficiently check whether the plan's coverage criteria have been met. Examples of how inclusion of the diagnosis on the script facilitates coverage decisions include:
    - **Zofran** or any anti-nausea or anti-vomiting drug is covered by Medicare under Parts A and B by most plans when used for "medical care and treatment", such as following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chemotherapy or for the prevention of post-operative nausea and vomiting. A use usually not eligible for plan coverage is nausea associated with seasickness for an upcoming summer cruise or fishing trip.

- **Botox Cosmetic** and its identical cousin Botox are aggressively marketed. Botox has approved uses for several conditions with doses substantially higher for cervical dystonia than for other medical uses. Botox Cosmetic for wrinkles is seldom (knowingly) an eligible plan expense. Since Botox is identical to Botox Cosmetic, it could be used as a cosmetic treatment. Having the diagnosis on the prescription as the representation of the physician's intended use is an efficient mechanism to determine whether the expense is eligible or ineligible for coverage under the plan.

- **Information on drug-drug interactions, warnings or cautions and when indicated, dosage adjustments**) is required by the statute. The Institute of Medicine has identified medication errors as a major cause of preventable death. To reduce and prevent widespread errors, The Institute of Medicine advocates "designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing". *Dx on Rx* is a system design that meets the Institute's criteria and facilitates the Medicare e-prescribing requirement to provide information on interactions, warnings or cautions and dosage adjustments. The following current practices increase the likelihood of medication error. A "systems design" of *Dx on Rx* can improve patient safety by helping to prevent medication errors.

  - **Same Drug; Multiple Uses:** It is common for one drug to have multiple uses. For each condition, where use is FDA approved or recommended by an authoritative group, the recommended initial dose and the duration of therapy can vary significantly depending on the needs of each patient and on their specific conditions. Without knowing the diagnosis, it is impossible to provide reliable information on dosage adjustments and other important warnings and cautions. Examples include:
    - **Prilosec**: Prilosec has eight approved indications. The recommended dose of Prilosec for an active duodenal ulcer is 20 mg once a day for a period of 4 weeks. Some patients may need an additional 4 weeks. However, if the patient has Zolinger-Ellison Syndrome, the recommended dose is 60 mg once a day, with continuous treatment.
    - **Coreg**: The appropriate dose when used for congestive heart failure would be 3.125 mg twice a day. But if Coreg is used for hypertension, the recommended dose is twice as high.

  - **Different Drugs, Different Uses, Confusing Names:** *Sometimes medication is selected in error because the names are similar with slightly different spelling or pronunciation.* Dx on Rx *allows prescribers, dispensing pharmacists, Pharmacy Benefit Managers (PBMs) – and more importantly – systems with artificial intelligence to check the diagnosis code against the dosing specific to the patient's condition. Examples of drugs that have been mixed up include the following:*
    - Imferon (an iron replacement) and Interferon (for cancer therapy)
    - Xanax (for anxiety) and Zantac (for ulcers)
    - Celebrex (for arthritis) and Celexa (for depression)
    - Quinine (for nocturnal leg cramps and treatment of malaria) and quinidine (for abnormal heart rhythms).


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*Dx on Rx* can help prevent medical errors and improve care. It's simple, easy, systems-driven, and effective. By avoiding mistakes, *Dx on Rx* improves patient care. It can be done routinely before a medication is dispensed or a claim is processed. Without knowing the diagnosis, it would be difficult to provide the information required in the statute, for example, dosage adjustments.

- ***Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed*** is required by the statute. Without knowing the diagnosis, accurate information about lower cost or therapeutically appropriate alternatives cannot be provided in many cases. In fact, too often prescriptions are written when there is no evidence that the drug is either appropriate or effective. Marketing efforts coupled with new products and more approved indications for an existing product have contributed to prescribing patterns that fall outside reasonable guidelines. There are many possible examples, including:
  - The patient "asked for it" or "expected it". Antibiotics are often cited as examples.
  - The medication was selected in error.
  - The medication was selected as an experimental approach without evidence. Neurontin is an example where aggressive marketing efforts resulted in 78% non-FDA approved use of the drug. There are reports that off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines.
  - The prescribing physician is involved in research that has not yet been published, but benefits to the patient are quantifiable and substantial. Best practice begins somewhere – and when substantiated as effective and appropriate, sharing with others sooner is to the benefit of all.

The diagnosis on the prescription indicates the physician's intended use. If the medication and intended use do not match, the dispensing pharmacist calls the prescriber. *Dx on Rx* can help clarify appropriateness of use and target availability of lower cost, therapeutically appropriate alternatives for the drug prescribed. It's simple, easy, systems-driven, and effective. *Dx on Rx* can improve patient care and be done routinely before a medication is dispensed or a benefit claim is processed.

- ***Information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved*** is required by the statute. The statue recognizes the importance of the medical history (medical history relates to information about the patient's health status, for example, allergies, laboratory test results and chronic conditions) and intends to propose standards for communicating medical history at a future date. Clearly, if medical history is important, current medical status (diagnosis) should be an even higher priority.

**2. *Dx on Rx* Complies with HIPPA**

The statute requires that information shall only be disclosed if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) under the Health Insurance Portability and Accountability Act of 1996. The


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department of Health and Human Services has confirmed that requiring a diagnosis or diagnosis code on a prescription requires no separate special authorization because it falls within the treatment, payment and healthcare operations category of the privacy rule.

However, it is recognized that there may be specific circumstances under which *Dx on Rx* is deemed inappropriate by the prescriber or patient, e.g., when doing so might compromise patient adherence to therapy or confidentiality. Therefore we suggest when it may be inappropriate to include the diagnosis or indication on the prescription, this information can be communicated to the pharmacy concurrent with the prescription being placed (verbally or written separately), or after the drug is dispensed. A concurrent transmission is preferred, as it prevents delay in dispensing and counseling, or the need to address dispensing or counseling errors after the fact. Any privacy concerned can be addressed and is not a barrier to implementing *Dx on Rx*.

**3. *Dx on Rx* is supported by adequate industry experience and doesn't require pilot testing.**

At this time, CMS can only propose to adopt as final standards, those standards with which there is adequate industry experience. Otherwise, pilot testing is required. While generally pharmacy benefits are unique in healthcare for paying claims submitted without requiring diagnosis or indication for service, there are at least three notable exceptions to this rule. We believe these exceptions provide adequate industry experience so that pilot testing would not be necessary. The three exceptions are as follows:

- **Medicare beneficiaries.** For the limited number of drugs covered by Medicare/CMS prior to the introduction of the Medicare Modernization Act (diabetic supplies, transplant drugs, etc.), there is no reimbursement for these drugs unless the diagnosis is submitted with the claim. Here the requirement is about fraud and coverage mechanics and not quality of care since there is no coverage review before the drug is dispensed.
- **Medicare/Medicaid nursing home residents.** The Institute of Medicine (IOM) issued a report in 1986 titled *Improving the Quality of Care in Nursing Homes*. One concern then was the widespread use, as chemical restraints, of psychopharmacologic drugs including anti-anxiety drugs, sleeping pills, barbiturates and antipsychotic drugs. That report led to Federal regulations which require that nursing home residents be free of all "unnecessary" drugs. To ensure compliance with these regulations, a patient's physician must document the indication for the use (Dx) of each drug (Rx) in a resident's medical record so that a pharmacist, as part of the federally-mandated Drug Regimen Review requirement, can review the complete medical record each month and report apparent irregularities to the individual who has the ability to correct them. While quality of care improvements and cost savings were anticipated results, the most common recommendation made by the pharmacist, and accepted by the physician, may have been unexpected by some. It is to discontinue Rx therapy because it is inconsistent with the diagnosis (Dx).
- **Veterans Administration (VA).** The VA hospital system began requiring *Dx on Rx* in 1993. In 1999 the electronic infrastructure had no space for the diagnosis but a new project is underway to reinstitute it. However, during the 6 year period when *Dx on Rx* was in place, the VA found something unexpected. By simply putting their health condition (i.e. high blood pressure) on the pill bottle, patient compliance to take the medication increased. This was in addition to improvements in quality of care and a decrease in prescribing errors.

**4. *Dx on Rx* Supports MMA Objectives**

*Dx on Rx* supports and facilitates the Medicare Modernization Act's cost control and quality improvement requirements. Specifically the MMA regulations state:



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- *Each plan sponsor must have established a drug utilization management program, a quality assurance program, a Medication Therapy Management Program and a program to control fraud, abuse and waste.*
- *A reasonable and appropriate drug utilization management program must include incentives to reduce costs when medically appropriate; maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.*
- *A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use…*

Knowing the diagnosis is key to any utilization management program. Without the diagnosis, presumptions and guess work replace fact-based decision making. In many cases, utilization management programs spend time and money to confirm a diagnosis so that utilization review can be performed. *Dx on Rx* not only supports and facilitates the MMA objectives, but it can reduce the need for prior authorization and other utilization management programs. The diagnosis would illustrate the prescribing physician's intended use and thereby eliminate or reduce the need to contact the physician. An efficient, fact-based process should translate to easier approvals (or denials) of prescription plan coverage with savings in the tens of millions to Medicare and Rx drug benefit plan sponsors.

*Dx on Rx* will facilitate the efficient approval of covered plan expenses and reduce the frequency or intensity of Prior Authorization procedures required by some PDPs and MA-PDPs.

**Conclusion**

E-prescribing is in its infancy. But it will grow up fast. Many will look to the Medicare e-prescribing standards as a model. *Dx on Rx* is both practical and doable. Patients deserve the advantages that *Dx on Rx* offers for:

- Preventing medical errors and improving care
- Highlighting the appropriateness of use, and
- Eliminating surprises by determining up-front eligible plan expenses.

*Dx on Rx* represents progress in terms of maintaining a viable Medicare prescription program by improving the quality of care while managing costs.

Sincerely,

Patricia L. Wilson

Patricia L. Wilson
Consultant



**Tel: 610-519-0602**
**Fax: 610-519-0605**

**Submitter :** **Mr. Shawn Bloom** **Date: 03/31/2005**

**Organization :** **National PACE Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-6-Attach-1.DOC

CMS-0011-P-6-Attach-2.DOC

March 31, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

RE: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Sir/Madam:

The National PACE Association (NPA), on behalf of its members, would like to submit the following comments regarding the proposed rule on E-Prescribing and the Prescription Drug Program.

For the most part we would like to use the comment as an opportunity to describe the manner in which PACE organizations currently provide prescription drug coverage and identify certain issues that we hope CMS will take into consideration with regard to applying additional Part D requirements to PACE organizations.

PACE organizations are comparatively small in size relative to other Medicare managed care providers. Moreover, our focus is on the direct provision of health care services, as opposed to operating a large health insuring entity. The largest of our 32 programs enrolls less than 2,000 enrollees; the average census at PACE programs nationwide is approximately 350. Primary medical care is generally provided directly by staff physicians who participate on an active interdisciplinary team (IDT) involving numerous additional professional and paraprofessional staff. PACE primary care physicians and other IDT members closely monitor the prescription drug use of all PACE enrollees and are well informed of the consequences of medication mismanagement on both patient outcomes and costs. If medical specialists, e.g. cardiologists, neurologists, etc., are involved in the delivery of care to PACE enrollees, they act primarily as consultants. In most cases, they make recommendations regarding prescription medications to the PACE primary care physician. The primary care physician then writes the prescription as requested by the medical specialist or, to the extent the prescription might interact with other medications the enrollee is on, etc., the primary care physician would contact the specialist to coordinate care.

In the vast majority of cases, prescriptions are written by the PACE primary care physicians. In this regard, we anticipate that many PACE organizations would not consider it advantageous or necessary to create e-prescribing capacity as a means of improving patient care. Consequently, the NPA would like to confirm that e-prescribing will not be mandated in the future. Further, to the limited extent that prescriptions may be written by contract physicians, we ask that CMS consider the impact of additional information systems requirements on PACE organizations, taking into account their size and overall approach to care coordination and service delivery. The implementation of Part D is already generating substantial additional administrative costs for PACE organizations – we are extremely concerned that additional requirements may make implementation of PACE prohibitively costly for prospective providers.

I would be pleased to discuss NPA's comment with you in more detail or respond to any questions you may have. I can be reached at (703) 535-1567 or shawnb@npaonline.org. Thank you.

Sincerely,

Shawn M. Bloom
President and CEO

March 31, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTENTION: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

RE: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

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Sincerely,

Shawn M. Bloom
President and CEO

**Submitter :** **Judith Cahill** **Date: 04/01/2005**

**Organization :** **Academy of Managed Care Pharmacy**

**Category :** **Pharmacist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

**Issues**

Background

See attachment

Provisions of the Proposed Regulation

See attachment

Collection of Information Requirements

no comment

Regulatory Impact Analysis

no comment

CMS-0011-P-7-Attach-1.DOC

AMCP Academy of Managed Care Pharmacy

April 1, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Delivered electronically to: [http://www.cms.hhs.gov/regulations/ecomments]

Subject: Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Centers for Medicare & Medicaid Services (CMS) on its proposed rule for E-Prescribing and the Medicare Prescription Drug Program.

AMCP is a national professional association of pharmacists who have responsibility for managing prescription benefits in the private sector for health plans and pharmacy benefit management companies. Our 4,800 members provide comprehensive services to the over 200 million Americans served by managed care organizations. They are responsible for a broad and diversified range of clinical, quality-oriented services, programs and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

Electronic prescribing is a tool that should be of great benefit to prescribers, dispensers and patients. The process improvements that e-prescribing will foster include:

- Patient Safety - drug utilization review and drug interaction checking at the time of prescription ordering rather than at prescription dispensing
- Quality of Care - reduction in medication errors, clinical decision support information for prescribers
- Efficiency - reduction in number of phone calls for prescribers, pharmacists and payors

The Medicare Modernization Act (MMA) establishes an e-prescribing program to be used for Medicare beneficiaries. The private sector should be encouraged to follow its lead when establishing its own e-prescribing programs.



100 North Pitt Street
Suite 400
Alexandria, VA 22314
P: 703-683-8416
F: 703-683-8417
800-827-2627

Proper implementation of an e-prescribing program will require a set of standards to ensure ease of use among all stakeholders. To fully implement the e-prescribing program, the set of standards must support the entire electronic prescribing industry, not just Medicare. The endorsing of one set of standards for all e-prescribing programs has many benefits, including:

- Ensuring consistency - all prescription information will be transmitted in the same manner regardless of the e-prescribing program
- Providing efficiency - programs will only need to adhere to one set of standards, and will not be required to use a different set for each program.

This consistency and efficiency will allow easier and more rapid implementation of e-prescribing programs.

The Academy is pleased to provide comments on the following specific areas of the proposed rule:

## Background

The comments that follow address specific issues found in the "Background" section of the preamble to the proposed rule.

### Definition of Electronic Media

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) defines electronic media to include both electronic storage media and transmission media, including the internet, extranet, dial-up lines, private networks and the physical movement of removable/transportable electronic storage media. CMS has asked for comments on:

- When to apply this definition to determine when prescribers and dispensers are electronically transmitting prescription information
- When should prescribers and dispensers be required to comply with the e-prescribing standards
- Whether the HIPAA definition is broad enough to embrace new technologies as they are developed

The Academy believes that the HIPAA definition adequately describes all current electronic media, and CMS should use it as the basis for the e-prescribing standards. It follows that programs that electronically transmit prescription information that meet the above criteria should be subject to and comply with the e-prescribing standards set by CMS.

Finally, the definition delineated in HIPAA appears to be broad enough in its scope to encompass possible advances in technology for the foreseeable future. The Academy believes that the definition does not require modifications at this time.

### Adequate Industry Experience with Proposed Standards

Under the Medicare Modernization Act (MMA), pilot testing of proposed standards for electronic prescribing is required if adequate industry experience with the standard is lacking.

100 North Pitt Street
Suite 400
Alexandria, VA 22314
P: 703-683-8416
F: 703-683-8417
800-827-2627

The National Committee for Vital and Health Statistics (NCVHS) held hearings with various groups of constituencies on e-prescribing standards while identifying and examining standards for possible adoption. CMS staff attended those hearings and concluded that there is adequate industry experience for the standards proposed in the rule, but is seeking additional input on this issue.

The Academy agrees with the CMS determination that the standards proposed in this rule are based on adequate industry experience. Further, the Academy wishes to emphasize the importance of the adoption of one standard for each type of transaction. As stated above, the adoption of one set of standards ensures consistency, improves efficiency and may lead to a more widespread adoption of e-prescribing programs in both the public and private sector.

**State Law Preemption**

According to the 2003-2004 Survey of Pharmacy Law[1] thirty-eight states allow for the electronic transmission of prescriptions. However, the scope and substance of state legislation varies widely. The MMA addresses preemption of state laws such that federal law would supercede any state law or regulation that is contrary to the standards or restricts the ability of the electronic transmission of medication history and information on eligibility, benefits and prescriptions with respect to Medicare Part D. CMS has proposed to interpret that section of the Act as preempting state law provisions that conflict with federal electronic prescription program drug requirements that are adopted under Part D. CMS views the statute as mandating federal preemption of state laws that are either contrary to the federal standards or that restrict the ability to carry out the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or pertain to Part D enrolled individuals. CMS has asked for comments on the interpretation of the scope of preemption, and whether it applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities.

Using strict adherence to the rules of grammar, the more narrow interpretation of the statute language endorsed by CMS appears to be appropriate. This means that the preemption of state regulations applies only to transactions and entities that are part of an electronic prescription drug program under Medicare Part D. However, the Academy believes that preemption of all state laws that would otherwise prohibit or fail to permit electronic prescribing and electronic transfer of prescription information must occur to promote successful implementation and uptake of e-prescribing in both the Medicare and commercial prescription drug programs.

**Approach to Adoption of Standards, "Adequate Industry Experience"**

CMS has proposed to adopt foundation standards for electronic prescribing. Their definition of foundation standards is "standards that do not need to be pilot tested because adequate industry experience with those standards already exists." CMS is soliciting comments on the criteria that will be used to assess "adequate industry experience." The criteria are based on testimony presented to the NCVHS and include:

- The standard is American National Standards Institute (ANSI) accredited

[1] National Association of Boards of Pharmacy Survey of Pharmacy Law, ©2003 NABP, Park Ridge, IL

- The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner, and
- The standard is recognized by key industry stakeholders as the industry standard

The NCVHS Subcommittee on Standards & Security has done extensive work in researching electronic prescribing, and that committee followed similar guidelines in making its recommendations for foundation standards. The Academy believes that the criteria proposed by CMS, which are based on those NCVHS guidelines, can appropriately be used to determine whether "adequate industry experience" exists for proposed electronic prescribing standards.

The National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5, Release 1 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1; NCPDP Telecommunications Standard Implementation Guide, Version 5, Release 1; and the Accredited Standards Committee (ASC) X12N 270/271 Eligibility Benefit Inquiry and Response, Version 4010 are the foundation standards that CMS has proposed for adoption. Although the standards proposed in this regulation are important foundation standards, they do not represent the full set of standards that will be necessary to implement an electronic prescription drug program effectively. CMS must ensure that NCVHS continues to research additional standards and identify those that will be required to fully implement the e-prescribing program.

**Provider Identifiers**

Although the MMA does not require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions, CMS is considering requiring the use of the National Provider Identifier (NPI) as the provider identifier for an electronic prescription program under Medicare Part D. The NPI is the preferred option because it is the standard that will be required under HIPAA. The effective date for the NPI is May 23, 2005, which marks the beginning of the implementation period. The NPI must be used in all standard transactions no later than May 23, 2007. NCVHS has recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and that the NCPDP HCIdea® for identifying prescribers in the event that insufficient numbers of providers have been enumerated when the Medicare Part D electronic prescription drug program becomes effective. It is unknown how many providers will have had an NPI enumerated by January 1, 2006, approximately 7 months into its implementation period. CMS is inviting comments on the possible use of the NPI for e-prescribing transactions; the earliest time when the NPI should be required for use, and alternatives to the NPI, particularly in the short term.

The Academy recommends that the NPI become the mandatory provider identifier for the Part D e-prescribing program upon its effective date of May 23, 2007. Until the mandatory implementation of the NPI, it should remain an optional identifier, and the use of supplemental identifiers will be necessary. Other provider identifiers that may be used until such time as the NPI is mandatory include:

- The NCPDP Provider Identifier Number
  This identifier is nearly universally accepted for retail prescription drug claim

transactions in the United States and may used to determine the dispensing pharmacy. Note: This identifier can only indicate the dispensing pharmacy and not the pharmacist who dispensed the medication. Pharmacists may apply for an NPI, and the NPI could be used to pinpoint the dispensing pharmacist.

- The Medicare provider number
  This identifier has broad acceptance, and could be used to determine prescribers. However, providers who do not participate in the Medicare program are not assigned a number, and could not be identified.
- HCIdea®
  This proprietary database of health care providers is an initiative of the National Council for Prescription Drug Programs (NCPDP). It is gaining acceptance as a prescriber identifier for use in retail pharmacy claims transactions, and includes both the NPI and Medicare provider number as elements within the prescriber record. According to testimony presented on August 17, 2004, by NCPDP to the NCVHS Subcommittee on Standards and Security, NCPDP estimates that the HCIdea® database currently contains 1.2 million records, or in excess of 86% of prescribers.[2]

**Formulary and Medication History Standards**

Adoption of standards for formulary representation and medication history would clearly enhance e-prescribing capabilities. Such standards would make it possible for the prescriber to obtain information on the patient's benefits as well as information on medications the patient is already taking. CMS is considering adopting an NCPDP standard for formulary and medication history based on the RxHub protocol.

A formulary is a continually updated list of medications which represent the current clinical judgment of physicians and other experts in the diagnosis and treatment of disease and preservation of health.[3] Prescription drug programs employ a Pharmacy and Therapeutics (P&T) Committees when making decisions about what drugs are to be included in their formularies. The P&T Committee regularly reviews a plan's formulary and ensures that the medications listed are appropriate to cover the medical needs of the plan's membership. Each plan tailors its formulary to meet the needs of its own population. The Academy believes that in considering standards for formulary and medication history that CMS adopt a standardized format for transmission of formulary information and not standardization of formulary content. Plans would then be able to provide the necessary information about their formulary in a uniform manner, but would retain the ability to make their own decisions about which drugs should be included for coverage.

## Provisions

The comments that follow address specific issues found in the "Provisions" section of the preamble to the proposed rule.

---

[2]Lee Ann Stember and Phillip D. Scott, NCPDP testimony to NCVHS Subcommittee on Standards and Security, August 17, 2004.

[3] AMCP's Concepts in Managed Care Pharmacy: A Series; Formulary Management. ©1998, AMCP, Alexandria, VA

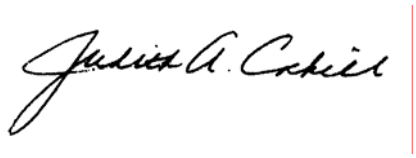
**Should Plans be Required to use the Standards for E-prescribing Transactions within the Enterprise**

The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with the electronic drug program standards once final standards are effective. Many closed networks currently conduct e-prescribing within the confines of their enterprise. They typically use Health Level 7 (HL7) messaging within a hospital or for a prescription transmitted to the organization's own pharmacy. NCVHS has recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards. The NCVHS recommendation differs from the HIPAA transaction requirements. The HIPAA Transactions Rule states that a covered entity that conducts a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard transaction.

This issue has been raised because of the numerous systems using several different transmission protocols in existence today. HL7 messaging is generally accepted within the hospital setting and some integrated health systems. Although the use of HL7 within the same enterprise is not HIPAA compliant, it does not appear that requiring these organizations to adopt new standards internally would be beneficial to promote electronic prescribing. The expense, both in dollars and time required, of acquiring and installing new compliant systems and training staff to operate them would be counterproductive and could delay implementation of the e-prescribing program indefinitely. As technology improves, and these legacy systems are replaced, CMS should require that any new or replacement system is compliant with the HIPAA transaction requirements.

AMCP appreciates this opportunity to submit these comments to CMS regarding the Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. If you have any questions about our comments, or require additional information, please do not hesitate to contact me at (703) 683-8416 or jcahill@amcp.org.

Sincerely,



Judith A. Cahill, C.E.B.S.
Executive Director

**Submitter :** **Mrs. Kristen Cusick** **Date: 04/01/2005**

**Organization :** **Quest Diagnostics Incorporated**

**Category :** **Laboratory Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-8-Attach-1.DOC

**Quest Diagnostics Incorporated**
815 Connecticut Avenue, NW
Suite 330
Washington, DC 20006
202.263.6260
202.728.0338 FAX

April 1, 2005

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
P.O. Box 8014
Baltimore, MD 21244-8014
Attention: Department-0011-P

Re: 70 Federal Register Page 6256ff. [Feb. 4, 2005]
"Medicare Program; Prescribing and the Prescription Drug Program; Proposed Rule"

File Code CMS-0011-P

Ladies and Gentlemen:

Quest Diagnostics, the nation's leading provider of diagnostic testing, information and services, and MedPlus, Inc. a subsidiary, appreciate the opportunity to respond to the Agency's NPRM Adopting Standards for an Electronic Prescription Drug Program. Attached are our comments and an executive summary is below.

Executive Summary:

- We support CMS' proposal to adopt foundation standards as final standards, but we have concerns about the ability of providers to conform to future standards without major regulatory changes.
- We recommend CMS adopt both the NPI and a unique patient identifier to avoid errors and mismatches of patient data.
- We support the preemption of all State laws affecting e prescribing to ensure unfettered interoperability.
- We believe that CMS, as authorized by changes in law if necessary, should broaden the proposed anti-kickback safe harbor and Stark exception to allow for free and fair competition and to facilitate the adoption of the e-prescribing standards.
- Finally, we believe that the NCPDP should be the arbiter of which versions of the e-prescribing standards are considered "current," which versions are considered "compatible" with the current version, and which versions should continue to be supported by "certified" vendors.

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed standards and future standards for e prescribing. Please do not hesitate to contact us should you have any questions about this information or need any further information. I can be reached at 202-263-6263 or Kristen.m.Cusick@questdiagnostics.com.

Sincerely,

Kristen Cusick
Director, Government Affairs

Attachment

**Comments of Quest Diagnostics Incorporated**
**on the Proposed Rule Adopting Standards for an Electronic Prescription Drug Program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003**

File Code: CMS-0011-P

Quest Diagnostics Incorporated ("Quest Diagnostics") is pleased to submit these comments on the proposed rule published in the Federal Register on February 4, 2005 regarding standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). Quest Diagnostics is the nation's leading provider of diagnostic testing, information and services. Quest Diagnostics offers the broadest access to diagnostic testing services through its network of more than thirty full-service laboratories in major metropolitan markets across the United States and in Mexico and the United Kingdom. Quest Diagnostics utilizes health information technology to provide insights that enable physicians, hospitals, managed care organizations and other healthcare professionals to make decisions to improve health. MedPlus, Inc., a subsidiary of Quest Diagnostics, offers an electronic prescription service to healthcare professional across the United States and would be affected by this proposed rule.

## I. Background

### *A. Statutory Basis*

1. *The scope of the proposed rule, as a practical matter, will be much broader than prescription drugs covered under the Medicare Part D program.* In the Statutory Basis section of the preamble to the proposed rule, CMS clarifies that the statute is applicable to covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically. The Medicare Prescription Drug Benefit final rule is similarly limited to requiring Prescription Drug Plan (PDP) and other Part D sponsors to support and comply with electronic prescribing standards for Part D eligible individuals. However, to be successful, standards for eprescribing and/or Electronic Health Records (EHRs) must be "interoperable" to a large extent. Therefore, in the interest of achieving the ultimate goal of interoperability in health care information data exchange, we support a broad interpretation of the statute, consistent with the aforementioned goal.

815 Connecticut Avenue NW • Suite 330 •Washington, DC 20006 • (202) 263-6260 FAX (202) 728-0338

Implementation of these eprescribing standards will require the cooperation of numerous healthcare industry participants (including prescribers, payors, PBMs, vendors and pharmacies), as noted by CMS. For example, to access patient medical histories, inpatient and outpatient healthcare facilities must implement the standards. Cooperation will mean, among other things, that these participants become a source of important patient information (i.e., all such parties must share patient data for the program(s) to achieve its purpose of interoperability).

We believe the standards adopted pursuant to Title I of the MMA will have a much broader impact on the prescription industry (and the healthcare industry as a whole) than the "technical scope" set forth in the rule. The practical effect of these regulations is that all electronic prescription systems will have to meet these standards. As a practical matter, PBMs or prescribers are not likely to invest in or take the time to comply with two or more different systems with different standards, one for Part D prescriptions and one or more for others.

2. *The definition of electronic media should be defined to clearly include electronic facsimiles.* In the preamble to the proposed rule, CMS invited comment on whether it should apply the HIPAA definition of "electronic media" to these regulations. We agree that it should apply the HIPAA definition, but believe that CMS should clarify that the term "electronic media," for purposes of the proposed rule, includes prescriptions sent by "electronic facsimile" to a pharmacy. The majority of prescriptions originating from eprescribing applications today are delivered via "electronic facsimile," as opposed to paper facsimiles and electronic data interchange (EDI) transactions. In the interest of uniformity and to avoid inconsistency of treatment, electronic facsimiles should be subject to the same standards as other electronic prescription transmissions.

3. *The foundation standards should be accepted as final standards.* We agree that adequate industry experience exists with respect to the proposed foundation standards such that CMS may adopt the foundation standards as final standards without pilot testing. However, please see the Comment in Section I.F.2. below regarding the use of specific version and release numbers.

4. *The final regulations should include Federal preemption of all other laws or regulations.* As CMS notes, the scope and substance of State activity varies widely among the States. We agree with various commentators that many (if not most) existing State laws were drafted with paper or possibly paper facsimiles in mind and, in fact, contain barriers that could impede the success of standard eprescribing programs. In addition, although we do not see any immediate conflict with the proposed foundation standards, we are concerned that conflicts with State laws will develop as further standards are proposed and implemented. For example, some States set forth with specificity the information that must be included in a prescription, the manner in which the prescription may be sent to the pharmacy, and (depending on the type of drug) whether the prescription can be sent at all. At a minimum, these regulations should clarify that Part D prescriptions may be sent electronically, by facsimile or by data interface exchange regardless of State law to the contrary.

State laws that mandate standards inconsistent with the standards contemplated by these regulations will retard the development and use of uniform eprescribing systems.

5. *The Anti-kickback Statute Safe Harbor and Stark Exception should be broader.* We understand CMS' position that it can only work with the statute as drafted. Notwithstanding, we believe it is important to point out the issues created by the statutory language and the limited safe harbor and Stark exception mandated by the statute. First, the statute requires that the safe harbor and Stark exception be limited to non-monetary remuneration (hardware, software, information technology, etc.) used solely to receive and transmit electronic prescription information. Based on our experience, we believe that dedicating software and equipment solely to a single function – such as eprescribing - is an unlikely business scenario, a waste of resources, and will result in extensive compliance costs and monitoring with limited benefits. Further, we believe that the list of those eligible for the protection of the proposed safe harbor and Stark exception programs would be too limited. The statute provides for a safe harbor and Stark exception for hospitals, group practices and PDP sponsors or Medicare Advantage organizations under specified circumstances in order to encourage implementation of electronic prescribing. We see no reason not to similarly protect laboratory companies or other provider/vendors who have a strong interest in the promotion of health information technology and the resources to assist their customers in its adoption. Indeed, to permit one group of providers or payers to provide eprescribing hardware and software while precluding another group of providers from offering eprescribing software along with their other electronic products will put the latter group of providers at a competitive disadvantage compared to the protected hospitals, group practices, and PDP sponsors. For example, the MedPlus Care360 system already has an eprescribing system that is packaged with the laboratory ordering and resulting system, but which is electronically locked down unless the provider pays for the eprescribing component. The adoption of a broader safe harbor and anti-kickback exception than has been proposed in this NPRM would permit the eprescribing component to become immediately available to thousands of providers at no additional cost to the healthcare system.

*B. The NCVHS Process*

No comments.

*C. Standards Design Criteria*

No comments.

*D Current Prescribing Environment*

No comments.

*E. Current E-Prescribing Environment*

No Comments.

*F. Evolution and Implementation of an Electronic Prescription Drug Program*

1. *The criteria are acceptable.* We support CMS's proposal to follow the three criteria set forth: (i) that standards be ANSI accredited, (ii) that the standard generally has been implemented by entities to which the final standard will be applied, and (iii) that the standard is recognized by key industry stakeholders as the industry standard. We agree that the proposed foundation standards are simply a starting point and that many further standards will be necessary to implement an effective electronic prescription drug program.

2. *NCPDP, not CMS, should be the arbiter of what versions of standards are current and compatible.* CMS notes that the NCPDP standards may be enhanced or revised in the future. We agree and, taking that fact into account, believe that references in §423.160 (b) and (c) to a specific "version" and "release" number and date of release introduce a degree of inflexibility into the rule. In fact, CMS acknowledges this issue in the discussion in Section II.E.2 of the proposed rule. Given the likelihood of periodic new versions and/or releases, we do not believe that having to make periodic changes to federal regulations are a practical or wise solution (even through the incorporation by reference update approval process referenced in the proposed rule). We believe a better alternative would be to allow NCPDP to determine which future versions and releases of the standards are considered to be compatible with the "current" version and a reasonable migration period during which certified vendors must continue to support previous versions. If CMS believes (through its own accord or complaints from industry sources) that NCPDP is not applying the criteria set forth in the proposed rule such as ANSI accreditation and wide industry acceptance, it can always "step in" at that time and revise the standards accordingly. This will allow for more flexibility in the industry without the necessity of valuable CMS time and resources yet leave a mechanism in place to protect industry participants in the event NCPDP ceases to be widely accepted as an objective/neutral organization.

3. *We support the current process for standard setting.* We generally support the process that has been utilized by CMS in establishing these foundation standards and propose that the process be continued. That is, public hearings conducted by the NCVHS Subcommittee on Standards and Security should continue to meet and should consider input from a variety of affected stakeholders and constituency groups.

*G. Electronic Prescription Drug Program*

1. *We support the immediate adoption of the NPI and the unique patient identifier.* CMS invited public comments on the possible use of the NPI as the primary identifier for Medicare Part D transactions. We believe there is general consensus nationally that a national provider identification number/system is necessary and will certainly satisfy the needs of the eprescribing Part D Programs. In our opinion, the discussion and issue then becomes the timing and availability of the NPI for meaningful use. We strongly believe that whatever final decision is made with respect to the NPI, all regulations applicable must be clear and mandate use throughout the healthcare industry.

The proposed rule is silent on an identifier that is even more vital for an effective eprescribing program – the unique patient identifier. Recognizing that CMS proposed and subsequently withdrew this proposed rule, we simply would underscore the necessity for such a unique identifier so that patient records from diverse sources may be properly and flawlessly matched. The adoption and implementation of a unique patient identifier would enable medical records to be matched despite misspelled names, nicknames, initials instead of names, maiden or hyphenated names and changes in address or other demographics - fields that in the absence of a unique patient identifier will have to be used to match patient records both within a provider's own systems and externally.

2. *We support an NCPDP standard for formulary and medication history that is based on the RxHub protocol.* We believe that RxHub has the only currently viable technology to allow providers meaningful access to formulary, benefits and medication history.

3. *We support the characteristics of future standards, as described by CMS, but we are concerned about the ability of providers to comply.* We generally agree with the characteristics that CMS set forth for development of the additional future standards as described in this section. However, we are concerned about the ability of all parties affected by the future standards to comply with them. With respect to medication histories and medical histories in particular, however, there do not exist any regulatory paths by which qualified EHR vendors or providers in the industry can access the data maintained by other EHR vendors or provider systems. As indicated elsewhere in these Comments, electronic prescription programs (as well as EHRs) are heavily dependent upon obtaining patient information from a variety of sources. Without the ability to access the information maintained by these other sources, eprescribing systems and EHR programs will have limited utility. Lack of access to patient information could result in one or a few parties (e.g., health plans or PBMs) developing proprietary systems that are effectively forced upon prescribers and pharmacies. This could have a negative cost impact and competitive effect on the industry.

CMS should ensure that providers receive already-authenticated requests, since individual providers will not have the resources or ability to authenticate every request for records – particularly in "real time." Authentication is an activity that might be a function of the National Health Information Network or RHIOs, but we reserve judgment until a proposal is made upon which we may comment. Furthermore, providers should only be required to fulfill authorized requests that are compliant with the eprescribing standards and which are requests for a disclosure that is compliant with the HIPAA requirements (i.e., for a valid treatment, payment or health care operations purpose and not, for example, a blanket request for data or some other unauthorized request). We are concerned that providers will not have the resources or ability to determine, in "real time," whether each such request is for a valid purpose under HIPAA.

*H. Summary of Status of Standards for an Electronic Prescription Drug Program*

We generally support the strategy that CMS has proposed for "phasing in" the implementation of the electronic prescription drug program standards. We believe the

foundation standards will provide a solid starting point for the adoption of eprescribing systems and standards by the industry.

## II. Provision of the Proposed Regulation

### *A. Proposed Change to Scope (Section 423.150)*

No further comments beyond Section I.A.1 of these Comments.

### *B. Proposed Definitions*

As noted above in Section I.A.2 of these Comments, we believe the HIPAA definition of "electronic media" should be accepted, but revised to clearly include prescriptions sent by "electronic facsimile" to the pharmacy.

### *C. Proposed Requirements for Part D Plans*

As noted in Section I.A.1 of these Comments, if the objective of the eprescribing rule is interoperability, we believe the statute should be interpreted broadly, consistent with that objective. To the extent consistent with the statute(s), we believe that Part D Plans and other affected parties should be required to respond in a compliant way to compliant eprescribing transaction requests external to the enterprise. Within the enterprise, it should be sufficient if the goals of the eprescribing standards are met, though not necessarily through standard transactions that are purely internal.

### *D. Proposed Requirements for Prescribers and Dispensers*

No comments.

### *E. Proposed Standards*

1. Prescription

No comments.

2. Eligibility

We support the adoption of the ASC X12N 270/271 transaction standards.

### *F. Compliance Date*

No comments.

In summary, we support CMS's proposed rule as described or clarified in these Comments.

- We support CMS' proposal to adopt the foundation standards as final standards, but we have concerns about the ability of providers to conform to future standards without major regulatory changes.

- We recommend CMS adopt both the NPI and a unique patient identifier to avoid errors and mismatches of patient data.
- We support the preemption of all State laws affecting eprescribing to ensure unfettered interoperability.
- We believe that CMS, as authorized by changes in law if necessary, should broaden the proposed anti-kickback safe harbor and Stark exception to allow for free and fair competition and to facilitate the adoption of the eprescribing standards.
- Finally, we believe that the NCPDP should be the arbiter of which versions of the eprescribing standards are considered "current," which versions are considered "compatible" with the current version, and which versions should continue to be supported by "certified" vendors.

Thank you for the opportunity to submit these comments. We look forward to working with CMS to finalize and implement the proposed standards and future standards for eprescribing. Please do not hesitate to contact us should you have any questions about this information or need any further information.

**Submitter :** **Dr. Alan Reyes** **Date: 04/01/2005**

**Organization :** **Dr. Alan Reyes**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Sirs:
This bill is yet another unfunded mandate that unnecessarily increases the cost of providing care. Regulators look at requirements like these as if money is meaningless but to those of us trying to provide care with ever shrinking reimbursement,the cost of using yet another special computer service is impractical.Health care is being destroyed one costly mandate at a time, and this is a prime example of wasted care dollars that would go to fund anything and everything except actually caring for patients.

**Submitter :** **Ms. Mary Myslajek** **Date: 04/01/2005**

**Organization :** **Ms. Mary Myslajek**

**Category :** **Individual**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Thank you for the opportunity to comment on this rule. Please contact me at 952-993-3063 if there are any questions.

**Issues**

Provisions of the Proposed Regulation

Re: CMS-0011-P G. Electronic Prescription Drug Program
+ Provider and Dispenser Identifiers (page 6262 -6263 Federal Register February 4, 2005)

The NPI (National Provider Identifier) should NOT be required on January 1, 2006. Any required use of the NPI should be no sooner than the required use of the NPI on other standard electronic transactions, namely May 23, 2007. Prior to that time legacy numbers should be permitted. Current Medicare provider numbers are available and should be used for the January 1, 2006 implementation of e-prescribing.

At this time, no NPI numbers have been issued. CMS has indicated that bulk enumeration of large segments of providers through associations or employers may not even be an option until late in 2005. Payers and providers in the health care industry confront significant cost and timing issues for the implementation of the NPI.

The focus of implementation timelines has been necessarily on the critical HIPAA transactions for claims, the 837P and 837I and remittance advices, the 835. Requiring the use of the NPI sooner on the e-prescribing transactions presents a hazard and burden for the industry. The hazard is that NPIs will not be readily available. The burden is that duplicate numbering systems will need to be maintained by providers and payers for certain transactions, thus not creating any simplification. Providers need to be able to obtain and implement NPIs in an orderly fashion rather than trying to move one type of transaction ahead of all others.

I urge you not to draw resources away from the methodical concurrent implementation of the NPI for all transactions.

**Submitter :** **Date: 04/04/2005**

**Organization :** **American Pharmacists Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-0011-P-11-Attach-1.WPD

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
3. The submitter had intended to attach more than one, but not all attachments were received.
4. The type of document provided was a password-protected file. CMS was given read-only access to the document.

We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Mr. James Schuping** **Date: 04/04/2005**

**Organization :** **WEDI**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

(See Attachment)

CMS-0011-P-12-Attach-1.DOC

# WEDI Comments to E-Prescribing NPRM

April 4, 2005


Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Re: E-Prescribing and the Prescription Drug Program NPRM

The following represent the comments of the Workgroup on Electronic Data Interchange (WEDI) for the Notice of Proposed Rule Making (NPRM) on the Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule. This proposed rule is referred to in the Federal Register as 42CFR Part 423.

Following publication in the Federal Register of February 04, 2005, the NPRM was posted to the WEDI web site. Subsequently, WEDI created an E-prescribing Workgroup tasked with the responsibility of formulating a WEDI response to the NPRM. Recommendations created by this workgroup were vetted during an audio cast forum titled the E-prescribing Policy Advisory Group (PAG). The PAG conference call was held on March 15, 2005.

These recommendations, along with comments to the proposed rule received during the PAG call, were presented to WEDI's Board of Directors on March 24, 2005 for their review and adoption as official WEDI recommendations. The following comments are the result of the WEDI Board's deliberations and represent WEDI's official positions on these issues. WEDI believes that the comments set forth in this letter represent the views of a broad coalition in the health care industry and we respectively request CMS to carefully consider these suggestions and recommendations to the proposed rule on E-Prescribing.

Very truly yours,

Mark McLaughlin
Regulatory Policy Analyst
McKesson
Chair, WEDI Board of Directors

T:\DORIS\CMS-0011-P\12.DOC
Los Angeles


# Recommendations from WEDI Board of Directors

# Medicare E-Prescribing and the Prescription Drug Program CMS-0011-P NPRM (42-CFR Part 423)

**This document contains recommendations from the WEDI Board of Directors on the Medicare E-Prescribing and Prescription Drug Program Notice of Proposed Rulemaking.**

**E-Prescribing NPRM**. The Centers for Medicare and Medicaid published a Notice of Proposed Rule Making (NPRM) that proposes regulations on electronic prescribing of drugs and prescription information for participants in the Medicare Part-D Drug Program. *'E-Prescribing'* is given a specific definition in the NPRM. Copies of the NPRM may be obtained at http://www.cms.hhs.gov/medicarereform/. Select **Medicare Part D Electronic-Prescribing Proposed Rule (PDF, 184 KB or Text)** NEW.

**Note on organization and format**. These notes are divided into two sections: (1) Primary Issues and (2) Additional Issues. Within each section, the notes are in the same sequence as the NPRM, using the same topic numbers and headings. Unnumbered headings are only for the convenience of the reader and are not found in the NPRM. Yellow text boxes are quotations from the NPRM.

## SECTION 1: PRIMARY DISCUSSION ISSUES

### I. Background

### A. Statutory Basis

**Topic 1**

### 2. State Preemption

> We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well. (F.R. page 6259)

**WEDI Recommendation:**

WEDI believes that federal preemption should be taken to a broader level than just Medicare Part D and should apply to paper as well as electronic prescriptions.

WEDI further believes that discrepancies in state board of pharmacy rules and regulations are a significant barrier to electronic prescribing and insert unnecessary costs into already thin margins.

Retail pharmacies must rely on electronic switch vendors, who have to assign high-level staff members to educate, petition, and obtain clarification and as well as lobby state boards of pharmacy (BOP) in certain circumstances, at considerable and unnecessary cost to the industry. (In its testimony in December 2004, the National Association of Boards of Pharmacy testified that all 50 states permitted electronic prescribing yet in its February 2005 Newsletter, SureScripts said that just 37 states were "good to go.")

Mail service and specialty pharmacies, as well as pharmacy benefit managers, must aggregate and reconcile different state rules, and ensure compliance with the specific rules applicable in the state in which the pharmacy filling each prescription operates.

Physicians rely on their software vendors, who must monitor board of pharmacy rules and modify their software systems to comply with them. The cost of a 50-state legal review, monitoring and software modification is absorbed by either the software company, or pushed back to physicians in the form of higher software costs.

Therefore:

- WEDI recommends Federal preemption of contrary state board of pharmacy (BOP) rules and regulations relative to electronic and paper prescriptions so that paper and electronic rules are complementary and synergistic.

- WEDI recommends that Federal preemption apply to all Medicare electronic and paper prescriptions, not just those covered under Medicare Part D.

    - WEDI recommends that Federal preemption have the same strong safeguards achieved by the states. In his December 8, 2004 testimony to NCVHS, the National Association for Boards of Pharmacy's Executive Director, Carmen Catizone, PharmD, said "NABP and the states are not opposed to federal pre-emption, but you have to make sure things occur with pre-emption. You have to look at why the states have certain requirements in place. … If you go with a very broad federal pre-emption that eliminates all the states' safeguards, what we would ask is that you put in place very stringent safeguards that mimic the states." WEDI agrees with Dr. Catizone.

- WEDI recommends that HHS review all 50 states BOP rules and regulations and determine a set of rules and regulations that will mimic the states' safeguards then consistently apply them to all states. Furthermore, keeping up with changing technology is a challenge for the states. WEDI believes modifications to BOP rules and regulations would be handled more efficiently at a

federal level. However, WEDI is concerned that Federal preemption that will reconcile BOP rules of the 50 states is highly complex and will take considerable time; therefore, WEDI recommends that the deadline for implementation of this aspect be in 2009. WEDI recognizes that this recommendation is out of scope for the NPRM. WEDI will draft a separate communication to HHS about this issue

**Topic 2**

**F. Evolution and Implementation of an Electronic Prescription Drug Program**

**Process for evolution of standards:**

We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS. (F.R. page 6261)

**WEDI Recommendation:**

WEDI recommends that a true private sector approach through ANSI accredited SDOs for standards development for e-prescribing is needed, with the federal government participating in the standards development process. We urge that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to what has been experienced with the HIPAA administrative transactions standards.

In addition, WEDI recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and any interested party should be eligible to submit proposals for additions and modifications. Further, a responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain the vocabularies. WEDI does not believe that it is necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

**G. Electronic Prescription Drug Program**

**Topic 3**

**Versioning of standards**

Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at §162.1101 through §162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. (F.R. 6261)

If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the **Federal Register** of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard. (F.R. page 6267)

**WEDI Recommendation:**

WEDI recommends that (i) HHS adopt minimal version levels of the standards, (ii) HHS depend on existing SDO enhancement processes for newer versions, and (iii) health care organizations be permitted to use newer versions provided there is backward compatibility. WEDI recommends NCVHS hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such change to HHS. If NCVHS considers the change to be substantive, as described in Federal Register Page 6267 above, HHS would issue a NPRM within 90 days. If the change is not substantive, it would waive notice and comment.

WEDI is concerned about any possible divergence between HIPAA standard transactions and the same transactions, such as the 270/271 eligibility inquiry, that are employed in this NPRM. WEDI recommends that procedures be designed to permit the changing needs of HIPAA and e-Prescribing to be met but that such modifications to standards do not result in multiple standards. WEDI also recommends consideration of implementation phases rather than requiring all transactions by a single date. Consideration should be given to adequate piloting and testing.

**Topic 4**

**Use of National Provider Identifier**

We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.

NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.

(F.R. 6263)

**WEDI Recommendation:**

WEDI believes standard identifiers are extremely important for these transactions. It makes the following recommendations:

- WEDI recommends that the NPI be the primary identifier for prescribers and dispensers.
- WEDI recommends that current identifiers be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access, are available.

- WEDI recommends that the required date for use of NPI in transactions in this NPRM must not be sooner than the required date for use of NPI in HIPAA transactions. WEDI is concerned that there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before NPI can be mandated. The NPRM date of January 2006 is unattainable because of non-availability of these NPI system capabilities. The NPI should not be required until the May 2007 deadline.

- WEDI is also concerned that legacy identifiers had capability for transaction routing that may not be provided by NPI or other data elements in standard transactions. This problem must be researched and resolved. Most likely the solution is will be with data in the transactions and thus no change to NPI rules.

**Topic 5**

**Formulary and Medication History Standards (F.R. page 6263)**

We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:…

(F.R. 6263)

**WEDI Recommendation:**

WEDI recommends that the formulary benefit and medication history messaging standards currently being developed should go through rigorous pilot testing prior to the release of a final rule by HHS.. Vendors should be factored into the regulations and encouraged to bring products to market that can assist physicians in complying with the statutory requirements prior to compliance dates. Because pharmacies and pharmacy benefit managers must have their systems operational in order to allow physicians to send test prescriptions that comply with new standards, the final regulations should provide for staggered implementation dates. Most physicians must rely on their vendors to provide them with the tools necessary to comply with the electronic prescribing program. Strong government leadership is critical to rapid and seamless conversion.

WEDI urges HHS to make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had an extremely difficult task of trying to resolve inter-governmental differences from across the Federal government in the Addendum to the Electronic Transactions and Code Sets rule. The additional time it took to resolve those differences left inadequate time for the various vendors to work with their customers (the provider and payer communities) to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long, and not conducive to industry usage.

**Topic 6**

**Medication history standards**[1]

We propose the following critical characteristics for medication history standards:
• The standards are accredited by an ANSI-accredited standards development organization.
• The standards permit interface with multiple product, router, and POC vendors.
• The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.
• The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription. (F.R. 6263)

**WEDI Recommendation:**
As similarly described in "*Process for evolution of standards"* above, WEDI recommends private sector development and maintenance of standards and that modifications and enhancements to standards not be hindered by extensive rule making processes.

WEDI is concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in

[1] Medication History transactions involve all entities in the healthcare arena (prescribers, pharmacies, payers, RHIOs, etc) and the patient.

responses to requests for a listing of a patient's drugs, or his or her medical history within a certain timeframe, are likely to be highly complex. WEDI recommends that the framework of the requisite controls be designed and explained.

WEDI is concerned that the current models for retrieving prescription and medical history is still underdevelopment and incomplete. For example, patients often utilize multiple pharmacies which makes the patient's full prescription record at any one site incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but rather to rule out a diagnosis, and a record of the outcome is not recorded.

**II. Provisions of the Proposed Regulation**

**E. Proposed Standards**

**2. Eligibility**

**Topic 7**

We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…

Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.

We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards[2]. … (F.R. Page 6266)

**WEDI Recommendation:**

- **Adopt ASC X12N 270/271 where Appropriate**. For eligibility inquiry and response, the HIPAA Transactions and Code Sets rule adopts the NCPDP Telecommunication Standard for pharmacy inquiry and the ASC X12N 270/271 for physician and other provider inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

[2] A clarification: Although the NCPDP Telecommunication Standard is EDI and was named in HIPAA, it is not based on EDI for EDIFACT and ASC standards.

- **Plans should be encouraged to respond with more than "yes" or "no"**. WEDI and the Council for Affordable Quality Healthcare (CAQH) are working together to improve the quality of the 271 eligibility response from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. In the current HIPAA 270/271 eligibility transaction a health plan may either give detailed benefit information or simply give a "Yes, this person has coverage", or "No, this person does not have coverage". Physicians need more detail than yes/no and they need the information in a more consistent manner. At a minimum, plans should respond whether the patient is covered and provide guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. WEDI recommends that E-prescribing standards support the findings of the WEDI/CAQH project.

  The goal of the WEDI/CAQH project is to encourage all health plans to respond to eligibility questions based on business rules established by the industry that are agreed to by health plans in concert with other key stakeholders, such as, healthcare providers, vendors, and X12. While this effort is just beginning planning has been in process and CAQH initiated the process in January.

- **Adopt NCPDP Implementation Guide for Standard Card**. In 1997 NCPDP adopted an Implementation Guide based on the INCITS 284 standard for a health care identification card for prescription drug plans. The NCPDP Implementation Guide complies with regulations mandated in more than two dozen states. INCITS 284, revised for NCPDP in 2004-2005, is designed to support health care identification for any type of health plan. To avoid conflicting card standards, WEDI recommends that HHS adopt the NCPDP Implementation Guide as the standard for the Medicare Part D Pharmacy ID Card Standard.

**IV. Regulatory Impact Analysis**

**Topic 8**

We invite public comment on our expectations for prescriber participation.

(F.R. Page 6268)

**WEDI Recommendation:**

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2012 with a slightly lesser cut in 2013. Concurrent with these cuts, the costs of care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40% less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to assist in the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment WEDI believes it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless this technology provides an irrefutable, tangible benefit both to their patients and their practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of electronic prescribing's promise of improved efficiency, patient safety and health care quality.

WEDI believes that e-prescribing offers significant financial and other benefit potential to providers. But that case may not appear compelling to many providers in the healthcare financial environment between now and 2014. WEDI recommends that CMS fund development of analysis and educational documentation which will ease the financial case for providers.

**SECTION 2: ADDITIONAL ISSUES**

**I. Background**

**Topic 9**

**A. Statutory Basis**

In the context of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) transactions and code sets (TCS) requirements, a covered entity that conducts a covered transaction using electronic media must comply with the applicable transaction standard. Electronic media is defined under HIPAA to include both electronic storage media and transmission media, including the "internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media." (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards. (F. R. page 6256)

**WEDI Recommendation:**

WEDI supports this definition.

WEDI recommends that the e-prescribing final rule should apply the HIPAA Security rules to the e-prescribing transactions.

**Topic 10**

**E. Current E-Prescribing Environment (F.R. page 6260)**

**WEDI Recommendation:**

From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. We urge that the final standards are flexible and scalable in an effort to encourage adoption from small to large health care organizations as well as low to high-volume prescribing physician specialties. Electronic prescribing standards must allow for basic stand alone electronic prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors, such as, clinical quality, safety, efficiency, and integration with existing management software and electronic medical record systems when making an investment.

Electronic prescribing is not just a local message. Prescriptions can be sent electronically almost anywhere in the U.S. There is a need for standards to which all parties must adhere. Without accepted standards, propriety communication may become prevalent. Today, over 85% of the community pharmacies have software enabled for electronic prescribing using the NCPDP SCRIPT Standard. Many physician technology vendors are in the process of adopting the SCRIPT Standard or they support the translation of HL7 messages to the SCRIPT Standard. The industry is already supporting use of electronic prescribing standards and will support requiring their use.

WEDI recommends that HHS encourage DEA to publish its long awaited decision on electronic signatures and that it be applicable to more than just highly controlled substances such that prescribers and dispensers do not have to implement multiple electronic prescribing requirements, but rather a single effective and practical method which will encourage the full benefits of e-prescribing.

**Topic 11**

**F. Evolution and Implementation of an Electronic Prescription Drug Program**

**Criteria to assess industry experience:**

We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria…

- The standard is American National Standards Institute (ANSI) accredited**.** We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs. … (F.R. page 6261)

**WEDI Recommendation:**

WEDI recommends that the first sentence of the first criterion listed above be modified to read:

**WEDI Recommended Wording of First Criteria**

- The standard is approved by a Standards Development Organization (SDO) that is accredited by the American National Standards Institute (ANSI). We propose this criterion because the ANSI process is open and based upon consensus; so accredited standards are more likely adequately to address, and effectively respond to, industry needs. …

**Topic 12**

**H. Summary of Status of Standards for an Electronic Prescription Drug Program**

We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:

• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).

• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).

• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard). (F.R. Page 6264)

**WEDI Recommendation:**

The industry has already adopted these standards, which meet the basic needs of the industry. We support these recommendations at a "minimum" version level.

WEDI encourages the movement toward new standard versions as soon as practical, following the process described earlier. In particular, it encourages moving to the new versions of the HIPAA 270/271 and the HIPAA 278.

WEDI recommends pilot projects, when they are indicated, in order to prove the standards not named as foundation standards will work in multiple environments. Pilot projects should address workflow issues and establish the business rules in order not to impose undue burden on physicians and pharmacies. WEDI recommends that demonstration pilots show achievable financial models for appropriately funding the acquisition of technology, training and support for electronic prescribing in various clinical settings. WEDI offers to assist CMS is structuring pilot

projects, education, surveys, and developing financial models, in accordance with WEDI's statutory advisory role.

In some cases, pilot projects may be indicated, not just for non-foundation standards with which there has not been adequate industry experience, but also for any standard already demonstrated but being proposed for use in new circumstances.

**Topic 13**

**CMS Approach**

While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability. (F.R. Page 6264)

**WEDI Recommendation:**

WEDI applauds this approach and fully supports it.

WEDI believes interoperability with many clinical terms is also very important. For example, some terms may be used differently in a hospital setting than in an ambulatory environment. Final standards may need to be enhanced, where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality, efficiency, facilitation of interoperability between the various electronic systems involved in the e-prescribing process. Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT Standard.

**II. Provisions of the Proposed Regulation**

**Topic 14**

**B. Proposed Definitions (F.R. Page 6265)**

***Dispenser*** means a person, or other legal entity, licensed, registered,

or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.

***Electronic media*** shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.

***E-prescribing*** means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.

***Electronic Prescription Drug Program*** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

***Prescriber*** means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.

***Prescription-related information*** means information regarding eligibility for drug benefits, medication history, or related health or drug information or a Part D eligible individual enrolled in a Part D plan. (F.R. Page 6265)

**WEDI Recommendation:**

WEDI recommends that the definitions above be written in more generic terms without the reference to Part D. Part D restriction should be included in the applicability rules. WEDI believes e-Prescribing regulations and voluntary efforts based on regulations are likely to evolve to Medicaid and other plans; therefore, definitions should not be restricted to the single initial plan.

**Topic 15**

**NCPDP SCRIPT Standard**

We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:
• New prescription transaction
• Prescription refill request and response transactions
• Prescription change request and response transactions
• Cancel prescription request and response transactions
• The following ancillary messaging and administrative transactions:
+Get message transaction
+Status response transaction
+Error response transaction
+Verification transaction
+Password change transaction (F.R. Page 6265)

**WEDI Recommendation:**

WEDI supports the NCPDP SCRIPT Standard as proposed above.

## IV. Regulatory Impact Analysis

**Topic 16**

### A. Overall Impact

We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis. (F.R. Page 6269)

**WEDI Recommendation:**

Without extensive surveying and research, WEDI does not believe it is in position to respond to questions about the impact of these proposed regulations may have on different types of participants. Instead WEDI leaves response to these questions to its specific constituents.

However, WEDI is positioned and willing to develop and analyze surveys for CMS, as well as, educational documentation, analysis and financial models In addition, WEDI offers its support and expertise in overseeing pilot and testing projects in accordance with its advisory role.

**WEDI E-Prescribing Committee**

| | |
|---|---|
| Lynne Gilbertson | National Council for Prescription Drug Programs |
| Bob Beckley | SureScripts, Inc. |
| Jean Narcisi | American Medical Association |
| Anthony (Tony) Schueth | Point-of-Care Partners, LLC |
| Peter Barry | Peter T Barry Company |
| James Schuping | EVP/CEO, WEDI |
| Mary Ryan | Medco Health Solutions, Inc. |
| Mark McLaughlin | McKesson; Chair, WEDI |

**Submitter :** **Ms. Anne Marie Bicha** **Date: 04/04/2005**

**Organization :** **American Gastroenterological Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment for complete letter. Thank you.

The notice of proposed rule-making proposes that ?health plans have a substantial incentive to subsidize the cost of physicians? adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance.? It is important to differentiate health plans from prescription drug plans (PDPs) to reduce potential confusion.

Consequences of medication-related problems (e.g., adverse events) resulting in physicians? visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient?s medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients? compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term ?health plan.?

Please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

CMS-0011-P-13-Attach-1.DOC

# AMERICAN GASTROENTEROLOGICAL ASSOCIATION

4930 Del Ray Avenue • Bethesda, Maryland 20814-2513
301-654-2055 • Fax 301-654-5920 • member@gastro.org

NATIONAL OFFICE
Executive Vice President
Robert B. Greenberg

**PRESIDENT**
Emmet B. Keeffe, MD
Stanford University Medical Center
750 Welch Road
Palo Alto, CA 94304-1509
650-498-5691
Fax: 650-498-5692
ekeeffe@stanford.edu

**PRESIDENT-ELECT**
David A. Peura, MD
434-924-0316
Fax: 434-924-0491
dap8v@virginia.edu

**VICE PRESIDENT**
Mark Donowitz, MD
410-955-9675
Fax: 410-955-9677
mdonowit@jhmi.edu

**SECRETARY/TREASURER**
Ian L. Taylor, MD, PhD
504-584-1783
FAX: 504-584-2945
ian.taylor@tulane.edu

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April 4, 2005

Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014.

RE: E-Prescribing and the Prescription Drug Program; Proposed Rule

Dear Dr. McClellan:

The American Gastroenterological Association (AGA) is the nation's oldest not-for-profit medical specialty society, and the largest society of gastroenterologists, representing more than 14,000 physicians and scientists who are involved in research, clinical practice, and education on disorders of the digestive system.

The AGA appreciates the ability to comment on the proposed rule for E-Prescribing and the Prescription Drug Program. We recommend clarification on the issue below for the final rule.

The notice of proposed rule-making proposes that "health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance." It is important to differentiate health plans from prescription drug plans (PDPs) to reduce potential confusion.

Consequences of medication-related problems (e.g., adverse events) resulting in physicians' visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient's medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients' compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term "health plan."

Thank you for consideration of our comments. If we may provide any additional information, please contact Anne Marie Bicha, AGA Director of Regulatory Affairs at 301-654-2055, ext. 664 or abicha@gastro.org.

Sincerely,

Emmet B. Keeffe, MD
AGA President

**Submitter :** **Mr. Barry Gershon** **Date: 04/04/2005**

**Organization :** **GlaxoSmithKline**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attached

CMS-0011-P-14-Attach-1.RTF

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
3. The submitter had intended to attach more than one, but not all attachments were received.
4. The type of document provided was a password-protected file. CMS was given read-only access to the document.

We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Mr. Mick Kowitz** **Date: 04/04/2005**

**Organization :** **ZixCorp**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Attachment

Regulatory Impact Analysis

See Attachment

Collection of Information Requirements

See Attachment

Provisions of the Proposed Regulation

See Attachment

CMS-0011-P-15-Attach-1.DOC

zixcorp. 2711 N. Haskell Ave. | Suite 2300, LB 36 | Dallas, TX 75204 | ph 214 370 2000

April 5, 2005
To: Centers for Medicare & Medicaid Services
Re: Response to CMS-0011-P

Zix Corporation respectfully submits its comments on the CMS proposed rules for e-prescribing.

As a leading vendor for e-prescribing and prescription management services, we are pleased that the government has realized that this technology is a viable, beneficial service for the healthcare community and support measures creating standards and policies for the industry. We believe these actions will help foster widespread adoption of e-prescribing and contribute to significant cost savings and reduction of medical errors.

ZixCorp's position in the healthcare marketplace has given our company close affiliation with many of the stakeholders involved in the proposed CMS rules, including payors, pharmacy benefit managers, hospital associations, and the physicians and medical office staff who are most directly affected. Our e-prescribing application is currently certified with RxHub and SureScripts. We are the e-prescribing vendor for the country's largest e-prescribing initiative in Massachusetts. We are also the technology behind MedsInfo-ED, a patient safety program of the Massachusetts Health Data Consortium (MHDC) that offers point-of-service access to dispensed prescription history information in emergency rooms, and which utilizes many of the proposed standards.

Our comments are based on real-world experience in this emerging e-prescribing market. We also operate and maintain a SysTrust-certified data center for millions of users of our e-prescribing and secure e-messaging applications that serves as the trusted hub of connectivity, predominantly for the healthcare industry. Thank you for giving us the opportunity to voice our opinion on this very important proposal. If you'd like to know more about ZixCorp you can visit our Web site at http://www.zixcorp.com/ or feel free to contact us.

Sincerely,

Rick Spurr
CEO, President, and Chief Operating Officer

zixcorp.

**eHealth Solutions**

# ZixCorp® Responses

# CMS-0011-P

Prepared for

## Department of Health and Human Services

Submitted By:
**Zix Corporation**
2711 N. Haskell Ave., Suite 2300
Dallas, TX 75204-2960

www.zixcorp.com

Contact Person:
**Mick Kowitz**
Phone: 513-701-6009
Email: mkowitz@zixcorp.com

Date: April 5, 2005

# Table of Contents

# 1.0 RESPONSE FORMAT

ZixCorp responses reference the Department of Health and Human Services, Centers for Medicare & Medicaid Services document, 42 CFR Part 423 [CMS-0011-P], RIN 0938-AN49, Medicare Program: E-Prescribing and the Prescription Drug Program (01-17master.pdf) and comment on the proposed rule.

# 2.0 BACKGROUND

## *2.1 Statutory Basis*

### *2.1.1 State preemption: scope of preemption, specifically relevant State statutes, page 17*

ZixCorp makes a great effort to understand State regulations regarding the e-prescribing process. In general, we agree with the proposed scope of State law preemption as outlined in CMS-0011-P, i.e., the preemption applies to State law provisions that conflict with Federal e-prescription drug requirements that are adopted under Medicare Part D.

In particular, it is ZixCorp's position that the preemption should apply to Medicare and Medicaid prescriptions, as the States have varying and disparate rules and regulations relating to prescriptions for Medicare and Medicaid patients. Monitoring the changes to these disparate rules and regulations requires significant effort, as does implementing the required software changes to develop and support different versions of the e-prescribing software and system.

Furthermore, it is our position that Federal standards developed for Part D transactions should be broadly applicable to all e-prescription transactions. Not to do so would be to require the e-prescribing industry to adhere to a patchwork of multiple standards at different levels of jurisdiction.

## *2.2 Evolution and Implementation of an E-prescription Drug Program*

### *2.2.1 Criteria to assess "Adequate Industry Experience", pages 28-29*

ZixCorp agrees that the stated criteria to assess "Adequate Industry Experience" — American National Standards Institute (ANSI) accreditation, proven implementation success, and recognition by stakeholders — establish a good initial framework for validation. These factors serve to support a degree of technical experience and viability but do not immediately indicate proven commercial viability or value-delivery enablement. We would recommend the addition of indicators related to user acceptance such as utilization metrics and total attributable business/transaction volume.

Although ANSI standardization is desirable, we also suggest that the existence of multiple implementations based on alternative industry standards or a consistent group of standards, which may lead the ANSI process, should be considered equivalently valid, in the presence of earlier achievement of the other criteria.

### *2.2.2 Process used to evolve currently adopted and additional standards, page 30*

ZixCorp supports the Administrative Procedures Act; however, in an emerging market it is difficult to enforce a public offering of documents that to date have only been viewable

through organization membership. Groups such as the National Council for Prescription Drug Programs (NCPDP) provide access to their standard documents through NCPDP membership, as does RxHub® through contractual membership.

We support making documents that deal with format and standard rules and changes available in a timely manner. Currently some of these documents change without appropriate public knowledge and their publication in the *Federal Register* would level the playing field.

Additionally, we recommend that the Federal government adopt a similar process as that used by standards-setting organizations such as ANSI and Health Level Seven® (HL7) for proposing, specifying, changing, and approving standards.

## *2.3 e-Prescription Drug Program*

### *2.3.1 Use of National Provider ID (NPI) and/or alternatives, page 37*

As recently as mid–February, NCPDP released the HCIdea® identifier for dispensers. This concept is new and adds to the complexity faced by e-prescribing companies and transaction hubs in building identifiers. Currently, there is no single source for mandated identifiers and we would support a national identifier for providers, dispensers, and dispensing organizations.

Every "hub" might reference these identifiers but they typically implement provider directories that incorporate their own unique identifiers as well. The regulations should establish a transition period for these new identifiers and mandate that the new identifiers be used between partners by the end of the transition period.

### *2.3.2 Formulary, benefit, and medication history standards, pages 37-41*

ZixCorp currently uses the RxHub Formulary and Benefit protocols as part of its system implementation. It is our opinion that this standard meets the National Committee on Vital and Health Statistics (NCVHS) requirements for inclusive information.

However, this standard relies upon the representative National Drug Code (NDC) supplied by the pharmacy benefit managers (PBMs) or health plans, a complicated variable. It is our recommendation that drug identifier standards be included, whether RxNorm or NDCs (excluding Universal Product Codes (UPCs) from re-packagers or PBMs).

### *2.3.3 Identify required standards, page 41*

ZixCorp agrees that the listed standards should be required to support an e-prescribing program. Today, while many of the organizations we interact with formally state that they comply with the standards, in fact, they impose additional requirements above and beyond the standard.

As our written testimony of May 24, 2004, to NCVHS indicated, we have been asked to implement wrappers and add fields to these standards beyond the ANSI accreditation stipulated in the NPRM, which results in additional development and quality assurance time. To avoid this in the future, we recommend that the standards approved through ANSI accreditation be adhered to precisely.

ZixCorp currently supports the NCPDP SCRIPT standard 5.0 and the ASC X12 270/271/997/TA1 transactions. Additionally, we support the current implementation of the

RxHub formulary file and the pending NCPDP drug history transaction. Also, ZixCorp has been required by many partners to make modifications by adding the aforementioned SOAP wrappers and other XML wrappers.

## 2.4 Summary of Status of Standards for an e-Prescription Drug Program

### 2.4.1 Proposed and currently used standards, page 43

The proposed standards are from the NCPDP SCRIPT standard Version (5.0), ASC X12N 270/271, and NCPDP Telecommunications Standard Version (5.1). ZixCorp recommends that the regulations explicitly state that in conjunction with using the 270/271 transactions, the 997 and TA1 message and error transaction be used to communicate routing, format, and error messages.

The reason for this inclusion is to promote the use of the true ASC X12N standard instead of transaction authentication and error processing through XML wrappers such as SOAP and other non-standard wrappers.

From our experience in implementing the transaction set with multiple plans and PBMs, many have non-standard implementations of the X12 transactions. This causes an increase in our development costs and time-to-market readiness.

### 2.4.2 Strategy for phasing-in implementation of an e-prescription drug program, page 43

ZixCorp agrees that a phased-in approach is appropriate in this marketplace. The adoption of future standards will depend greatly on the concept of a national patient identifier, drug utilization standards for EHR, and other unknown datasets.

It is our position that SCRIPT standard and ASC X12N 270/271 transactions are central to the effective implementation of e-prescribing. As prior authorization standards and other standards become available, the industry will adopt them appropriately based on the Administrative Procedures Act.

### 2.4.3 Approach to interoperability, page 45

ZixCorp's opinion is that interoperability between EHR systems and e-prescribing systems is critical to the growth and long-term adoption of e-prescription technology. Many physicians will eventually perform e-prescribing tasks through EHR systems, however, for the foreseeable future (3-5 years) e-prescribing systems will be the fastest and most cost-effective approach for transmitting prescriptions electronically — especially for smaller practices. When the time comes for practices to migrate to EHR, interoperability will be essential to the practice and the standards will assure a smooth transition. However, until that time, EHR vendors should be required to comply with the stated e-prescribing standards in the same manner as e-prescribing systems to maintain continuity in the industry.

The ZixCorp e-prescription system is an open-interface architecture. We enable bi-directional HL7 integration and client-side integration of our application. We provide data to third-party sources such as PBMs, health plans, and other point-of-care solutions including practice management software and EHRs.

It is our opinion that basic core integration can be achieved by specifying required standards. It is our opinion that over the next two years industry standards will become apparent by necessity and will make implementation of the new rules easier.

ZixCorp supports the current approach to interoperability to gain insights and determine next steps. If vendors implement their system architectures correctly, this approach will be achieved and should not adversely impact current implementations.

# 3.0 PROVISIONS

## *3.1 Proposed Definitions*

### *3.1.1 Electronic media, page 47*

Electronic media are defined and expressed with the conceptual notion that all electronic media are transmitted through "wired" connections. This definition is flawed because it does not address the issue of prescription information that is created at the point of care on devices that are wirelessly connected. In fact, more than half of the prescription information created at the client device for the electronic transmission of prescriptions is sent via a wireless network connection.

Information management is often addressed at a server farm where data is manipulated and then transmitted to third-party dispensers; however, the information is created and moved electronically from the point of care via wireless communications. This is not addressed in the document, yet the Medicare Modernization Act of 2003 specifically identifies the protection of patient rights as one of the purposes of the Act.

ZixCorp therefore recommends that the section dealing with network protocols that would exist in a wired network be expanded to include reasonable best practices for securing wireless communication.

## *3.2 Proposed Requirements for Part D Plans*

### *3.2.1 Use of e-prescribing transaction standards within the enterprise, page 49*

Organizations must be able to interact with one another to ensure patient safety and reduce medical costs. ZixCorp's opinion is that this philosophy is inherent within any healthcare organization.

In many cases, healthcare facilities also work with internal vendors (i.e. their own staff) that are required to interoperate. While we would expect that standards make it easier for facilities to internally integrate disparate systems, we do not recommend that an organization be required to adhere to standards internally.

If third-party vendors are brought into these facilities, they will most likely have implemented the e-prescribing standards. If the facility has already built an internal system that communicates to the third-party system through a custom interface, converting to the standards could be a financial and time-consuming burden on the facility.

Our position is that internally created systems should not be mandated to communicate using the standards if an interface already exists and is operational. If the internal systems are communicating to other internal systems, they should not be required to implement the standard. Any externally facing interface should be required to comply with the standards.

## 3.3 Proposed Standards

### 3.3.1 Adopt ancillary prescription messaging and administrative transactions in NCPDP SCRIPT, page 55

ZixCorp's suite of NCPDP SCRIPT implementations includes all SCRIPT standard transactions and ancillary transactions. While implementation is slightly different among transaction hubs and individual pharmacies accepting these transactions, it is our opinion that they are business-based differences that still meet the core definition of these transactions.

There most likely is adequate industry experience based on existing implementations and therefore these transactions would not require pilot testing.

### 3.3.2 Coordinate eligibility update process when e-prescribing and HIPAA standards are the same, page 59

We recommend that CMS reference the relevant HIPAA standard so that the standard will be updated automatically in concert with any HIPAA standard modification.

# 4.0 IMPACT ANALYSIS

## 4.1 Overall Impact

### 4.1.1 Expectations for prescriber participation, page 66

ZixCorp's position is that the key to prescriber participation in e-prescribing programs is an integrated approach that encourages the vendor, prescribers, regional payors, and PBMs to collaborate on all aspects of prescriber recruitment, deployment, and retention in local healthcare communities.

The estimate of growth in e-prescribing of 10 percent per year is reasonable, but is contingent upon incentives or sponsorships for physicians to e-prescribe. These incentives or sponsorships should be borne by the payors, since they have the greatest financial benefit from e-prescribing, but other parties, including physician organizations, pharmaceutical companies, and other entities may be willing to provide them. Another incentive might be reduction in malpractice premiums. Without these incentives, or a Federal mandate, it is unlikely that physicians will adopt e-prescribing at the estimated rate.

Publicity surrounding e-prescribing and the Medicare Prescription Drug Program will no doubt heighten prescriber awareness of benefits and options. We recommend that the Federal government commission studies around the individual e-prescribing solutions and publicize the results to the prescribing community.

### 4.1.2 Cost and saving estimates, page 71

Our opinion is that e-prescribing provides measurable benefits to physicians, patients, pharmacists, health plans, and pharmacy benefit managers. Of these, health plans and PBMs generally benefit the most financially.

Health plans and PBMs benefit by improved generic dispensing rates, formulary compliance, and mail order utilization. Formulary and generic improvements achieved with e-prescribing vary by plan benefit design but generally are 1-4% or more per year over

traditional prescribing. In addition, mail order rates are improved as the physician is reminded of this benefit when available. Mail order improvement rates also vary by plan benefit design and are generally 1-3% or more per year. Actual dollar amounts related to these savings vary by drug purchase price and market.

Health plans and PBMs also benefit from improved formulary compliance by better drug purchasing power as related to drug rebates. These rebate amounts vary widely based on many criteria including member group distribution (union, Medicare, etc.), market coverage, and drug volumes. In addition, health plans benefit from potentially reduced medical costs as a result of reduced adverse drug events. In one of the few studies to examine medical cost changes with e-prescribing, a Tufts Health Plan analysis showed a 19.3% reduction in medical cost increase as compared to a control group.[1]

Benefits for physicians include substantial time savings, specifically around the renewal process. Two separate studies showed approximately two hours of savings per physician per day (Tufts Health Plan Pilot Program[2] and Newton-Wellesley Case Study[3]). The physicians saved time because of fewer phone calls from pharmacies, health plans, and patients; calls were reduced because physicians had drug formulary status and patient medication lists on their e-prescribing devices.

Patients react positively to their physicians using advanced technology to care for them and are pleased to have their prescriptions waiting for them when they arrive at the pharmacy.

Pharmacists are more efficient in fulfilling prescriptions received electronically because the prescriptions are more legible and require fewer callbacks for clarification. The prescriptions are also less likely to have drug interaction alerts or require pre-certification, as the physician was aware of these issues at the point of prescribing.

## *4.2 Impact on Health Plans/PBMs*

### *4.2.1 Health plan costs and financial benefits, page 72*

It is ZixCorp's position that health plans, as the primary financial beneficiaries of e-prescribing, should bear the initial financial burden of sponsoring key physicians who treat a large share of their members. After the physician has been enjoying the efficiencies of e-prescribing for a period of time, the physician should pay any ongoing fees to continue access to e-prescribing.

Health plan full service sponsorship costs are above $1,500 per physician. This covers all costs of implementation, training, and retention for the first year. The financial benefits to health plans are primarily through improved formulary compliance, generic dispensing rate improvement, and an increased utilization of mail order services. The exact amount of these benefits varies due to many factors including plan benefit design, market share, covered lives, and local market competition.

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[1] Tufts Health Plan Pilot Program, Zix Corporation, 2003.

[2] Tufts

[3] Newton-Wellesley Internists Case Study, Zix Corporation, 2004.

It is our opinion that in general, plans can save approximately $40 every time a drug is switched from a non-preferred formulary or off-formulary drug to a generic.[4]

Additional savings may also accrue through reduced medical costs as a result of fewer adverse drug events. The cost of these adverse drug events varies by the severity of event as well as any co-morbidity factors with the patient's health. It is not uncommon for these adverse events to involve any or all of the following: office visit, ER visit, hospitalization, and lab tests.

The per-physician cost for a health plan to sponsor e-prescribing or to provide incentives to e-prescribing is modest compared to the potential savings from helping physicians to prescribe more cost-effective medications. However, the cost savings will not accrue if physicians decline to utilize the technology because they are unwilling or unable to bear the modest cost burden. Therefore, health plans should be actively encouraged by CMS to provide sponsorship and incentives for e-prescribing implementation.

#### *4.2.2 Health plan gross or net savings (after subsidizing prescribers to adopt e-prescribing), page 73*

It is ZixCorp's opinion that health plans should see a complete return on their sponsorship investment for subsidizing prescribers within the first 12-18 months after those physicians are fully implemented. Health plans will continue to receive financial benefits during subsequent years as those physicians continue to utilize e-prescribing.

Furthermore, our opinion is that health plans would additionally benefit should they receive favorable tax considerations for investments in e-prescribing programs. Specific e-prescribing grants would enable smaller or not-for-profit health plans to sponsor physicians. These incentives are key in the development of e-prescribing in small markets.

#### *4.2.3 Health plan e-prescribing incentive programs impact on plans and providers, page 74*

It is our opinion that health plan-sponsored physician incentive programs can be effective when structured appropriately. Health plans should incent physicians to use e-prescribing programs rather than give the physician funds for implementation. In this way, physicians are encouraged to use the e-prescribing system and benefits accrue to the health plan, physician, and other stakeholders in the prescription process.

### *4.3 Impact on Prescribers*

#### *4.3.1 Transition costs related to e-prescribing standards, page 76*

It is ZixCorp's position that e-prescribing usage costs for proven e-prescribing applications should not increase as a direct result of the new standards requirements since proven vendors have already implemented many of these standards. Much of this has been fostered by the standards bodies and the various transaction hubs.

[4] Pharmacy Benefit Managers: Tools for Managing Drug Benefit Costs, Quality, and Safety, prepared for Pharmaceutical Care Management Association by Health Policy Alternatives, Inc., August 2003.

Vendors that have not implemented these transactions will need to go through certification processes with the different transaction hubs that will help facilitate and normalize the implementation of the standards. They could incur more costs to update their systems and may need to pass these costs on to their users or sponsors. Additionally, many vendors may find it difficult to implement these standards. Once implemented, however, the benefits within the industry become far greater to them and everyone. While it may take longer to go through the process of implementing these transaction sets, in our opinion that is an achievable goal.

### *4.3.2 Health plan e-prescribing incentive programs, page 77*

Health plans are currently in various stages of evaluating e-prescribing programs, some of which involve incentives. Most often, these programs are structured so as to offer higher incentives with higher e-prescribing use. Currently programs such as Bridges to Excellence as well as several programs offered by Blue Cross Blue Shield of Massachusetts reward physicians for improving care, usually by implementing and using e-prescribing or EMR technology in their practices.

We anticipate that as e-prescribing program results are more widely known, health plans will be more aggressive in implementing these programs, which include incentives for continued use. Physicians who use the systems for all of their prescriptions should be rewarded with higher incentives relative to others who use e-prescribing systems for only some of their prescriptions.

### *4.3.3 Provider savings, especially solo and small group practices, page 78*

It is ZixCorp's opinion that smaller physician offices are at an economic disadvantage compared to larger offices in terms of their ability to purchase e-prescribing and especially EMR systems. Their smaller size, however, can work to their advantage. They are more nimble and generally not as risk-averse as are some larger offices. This makes them better suited to 1) make a decision to adopt e-prescribing more quickly, 2) implement the e-prescribing system in less time (smaller offices have fewer office staff and are often easier to schedule for training) and 3) because of their size, they often can't afford the more elaborate EMR systems making the efficiency, time savings, and relatively low monthly cost of e-prescribing to be a particularly good fit.

Several studies[5] have shown a significant time savings with e-prescribing of approximately two hours per physician per day. This benefit of increased efficiency is especially important to smaller offices with fewer internal resources and in our estimation far outweighs the nominal monthly access fees.

### *4.3.4 Provider cost – benefit information, page 79*

Medical offices benefit from e-prescribing by reduced pharmacy call volume, and larger offices may even benefit more — we estimate that with the higher volume of avoided calls, larger offices may actually be able to redirect or eliminate resources dedicated to processing pharmacy calls.

It is ZixCorp's position that the initial costs for implementing an e-prescribing system should not be borne by physicians. Health plans and/or PBMs should, as the primary financial

[5] Tufts Health Plan Pilot Program, Zix Corporation, 2003, Newton-Wellesley Internists Case Study, Zix Corporation, 2004, Framingham Pediatrics Case Study, Zix Corporation, 2004.

beneficiaries of e-prescribing, bear that initial cost. However, after the first year, the physician should pay for any monthly access fees or for additional physicians who join the practice. ZixCorp charges a small monthly access fee to physicians after the first year of use.

Physicians do have a disruption cost and learning curve associated with implementing e-prescribing. They usually need four to six weeks to fully incorporate e-prescribing into their daily routines and an additional eight to twelve weeks to realize the full benefits with respect to practice efficiency, personal productivity, and cost savings. In addition to reduced pharmacy phone calls, physicians benefit from potentially better medical outcomes and knowing that prescribing electronically is safer for their patients.

Our position is that the e-prescribing adoption success rate is directly tied to the ability of the physician to use the system for all or for the majority of their patients. Therefore, CMS should not try to implement an e-prescribing solution that enables providers to only prescribe for Medicare Part D beneficiaries, since it will likely fail.

## *4.4 Impact on Pharmacies and Other Dispensers*

### *4.4.1 Pharmacy impacts, page 81*

It is ZixCorp's position that pharmacists will greatly benefit from the efficiencies of e-prescribing. Studies have shown that pharmacists are very satisfied with e-prescribing rating it 4.67 on a 5-point scale where 5 = very satisfied.[6] In addition, this study reported that pharmacists saved an average of almost an hour a day. This study covered faxed e-prescriptions.

Currently most e-prescriptions being sent to pharmacies are sent via fax. This hampers the ability for both providers and pharmacists to track information and prevents efficiencies that utilization of an electronic process would promote. It is our opinion that full EDI to the pharmacy management system will further increase the value for pharmacists.

The major impact of EDI on pharmacies is the ability to receive electronic transmissions, which reduces the risk of losing paper prescriptions and eliminates the paper trail in the pharmacy. Additionally the electronic transmission of both renewals and new prescriptions increases transactional integrity in the pharmacy and reduces duplicate data entry.

## *4.5 Impact on Others*

### *4.5.1 Impact of e-prescribing on healthcare information technology vendors, page 82*

ZixCorp is a trusted provider of secure Internet services and applications. The PocketScript e-prescribing solution is one of the premier products in the marketplace. Yet because so many plans, pharmacies, and PBMs still do not support the proposed transaction standards, integration with our partners has required a great deal of development work and its associated cost.

We agree that the growth of e-prescribing provides business potential for healthcare information technology vendors. In addition, we estimate the cost to healthcare technology vendors will vary depending on the extent to which they have already adopted the

[6] Tufts Health Plan Pilot Program, Zix Corporation, 2003

recommended e-prescribing standards into their products. The impacts should generally be minimal because these standards were taken from the industry itself.

#### *4.5.2 Impact on other healthcare organizations, page 82*

It is ZixCorp's opinion that as e-prescribing continues to grow beyond its current adoption levels of 8-18%, other companies with interests in pharmacy or healthcare will necessarily be drawn towards it.

- Pharmaceutical manufacturers will likely invest in ways to promote their products because of the efficiency inherent in delivering their product messages directly to the physician.
- Medical device manufacturers such as makers of diabetes monitoring equipment will integrate their products with e-prescribing devices and offer physicians broader information for prescribing and therapy decision-making.
- Health content providers will also be aggressive in marketing their information products to e-prescribing vendors.
- Disease management information providers will devise ways to integrate their targeted medication compliance and protocols into point-of-care e-prescribing devices.
- Specialty pharmacies will promote e-prescribing to certain specialists to better enable them to send specialty prescriptions to their mail order facilities for fulfillment.
- Medical organizations will become engaged with e-prescribing, possibly certifying certain vendors on behalf of their members.
- EMR and EHR vendors will begin to incorporate proven e-prescribing systems into their suite of offerings. This interoperability will allow physicians a true evolutionary path from e-prescribing through EMR and EHR while enabling them with more choices for their e-prescribing tool.

## *4.6 Impact on Small Business*

#### *4.6.1 Impact on small entities regarding initial regulatory flexibility analysis, page 85*

We do not disagree with the conclusion stated in the proposed NPRM relating to the impact of the NPRM on small entities.

## *4.7 Effects on States and Federalism Statement*

#### *4.7.1 Input from states concerning State law preemption, pages 87-88*

Our views relating to the scope of State law preemption are stated above in response to section 2.1.

## *4.8 Conclusion and Alternatives Considered*

### *4.8.1 Suggestions for improvements, pages 88-90*

ZixCorp congratulates CMS on the process and questions laid out in CMS-0011-P, which present a very well-thought-out proposal for the implementation of e-prescribing to Part D entities.

It is our opinion that upon review of these comments, the Committee will recognize that a pilot of “real world” quality will be of tremendous value. The pilot must be administered in such a way as to allow e-prescribing vendors, pharmacies, and PBMs to follow their existing implementation strategies.

**End of document**

**Submitter :** **Ms. Kelly Lavin** **Date: 04/04/2005**

**Organization :** **American Osteopathic Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-16-Attach-1.DOC

*Department of Government Relations*

AMERICAN OSTEOPATHIC ASSOCIATION

1090 VERMONT AVE., NW, SUITE 510 • WASHINGTON, DC 20005 • (202) 414-0140 (800) 962-9008 • FAX: (202) 544-3525

*D.O.s: Physicians Treating People, Not Just Symptoms*

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Via: http://www.cms.hhs.gov/regulations/ecomments

**Re: Medicare Program; E-Prescribing and the Prescription Drug Program (02/04/05 Federal Register)**

Dear Dr. McClellan:

Thank you for the opportunity to provide comments on electronic prescribing (e-prescribing) and the Medicare prescription drug program (Part D). The American Osteopathic Association (AOA), which represents the nation's 54,000 osteopathic physicians, practicing in 23 specialties and subspecialties, supports ongoing efforts to develop and implement health information technologies (HIT).

The AOA is committed to advancing the utilization of technology in the practice of medicine. E-prescribing offers a unique opportunity to improve the quality of patient care and increase the efficiency in the disbursement of prescriptions.

The rapid development of medical informatics is changing the face of the healthcare delivery system. It is imperative that these technological advances occur through a deliberative process in which physicians and other interested parties are able to provide input and ultimately shape the end product. If done with careful deliberation and consideration for the various issues that arise with implementation, e-prescribing and HIT have the potential to be a driving force in enhancing the quality and efficiency of the healthcare delivery system.

In July 2004, the AOA House of Delegates created seven principle guidelines on e-prescribing. These seven guidelines serve as a framework for the development and adoption of electronic prescribing standards and technology. Application of these principles will assist our physicians in providing the highest possible level of care to our patients:

1. **Safety**: The units used to prescribe electronically should clearly show safety alerts. These alerts should be distinguishable from advertisements. In our opinion, advertisements adversely impact efficiency and offer no clinical benefit.

2. **Privacy**: Privacy of the patient must be protected. Information on patients' medications should be current, comprehensive, and compliant with standards set forth in the "Health Insurance Portability and Accountability Act" (HIPAA).
3. **Transparency**: All third party involvement in an electronic prescribing system must be clearly identified.
4. **Design**: The development of any system must ensure that the physician-patient relationship is protected to ensure that doctors in conjunction with their patients dictate the care, not computer software. In addition, the system must be designed in a manner that ensures that new health care errors are not introduced into the health care delivery system.
5. **Integration**: Systems should be proven and integrated into existing health information technology. E-prescribing can be an important component of a larger electronic medical record.
6. **Scalability**: Any standards should be broad-based and applicable to all health care delivery systems.
7. **Timing**: Standards should be implemented in a manner that allows software vendors and physicians adequate time to become compliant. In addition, we strongly advocate for broad testing of technologies and standards to ensure efficiency and effectiveness.

The AOA stands ready to work with you on the development of e-prescribing standards and technologies that are designed and implemented in a manner that enhances the quality of care our patients receive and assists with the efficiency of delivering health care services. E-prescribing offers great potential if all interested parties remain part of the process.

The AOA understands that physicians are not required to write prescriptions electronically. According to the proposal, physicians and other providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is transmitted electronically.

While the AOA agrees e-prescribing potentially increases safety and efficiency and could lower the costs of health care, we do not believe that this should become -- at any time -- an unfunded mandate on physicians. For this reason, we support the establishment of grant programs that will assist physicians, especially those in small group or solo practices, with the capital investments associated with HIT. For practices that are not yet electronic, the cost is a barrier.

Osteopathic physicians represent 18 percent of all physicians practicing in small towns and rural areas with populations of 10,000 or less, and 22 percent of all physicians practicing in communities of 2,500 persons or less. Financial incentives must be created to offset the cost of initial investment particularly for physicians and other health care providers practicing in lower income, rural and underserved areas.

Our comments to the proposed rule are as follows:

BACKGROUND
A. Statutory Basis

The AOA is working to ensure that physicians have the ability to afford new health technologies. Physicians, especially those in small practices, are facing financial difficulties with funding their own technologies. Providing a safe harbor under the Anti-kickback statute and an exception under the Stark law for certain non-monetary remuneration related to e-prescribing information technology items and services would help greatly to break down the monetary barrier that prevents technology adoption.

We look forward to the separate publication of rulemaking for the Stark Exception, as well as the new safe harbor under the anti-kickback statute, which will be proposed by the Office of the Inspector General (OIG). We urge CMS and the OIG to release proposed rules as soon as possible. We ask that the exception and safe harbor pre-empt any state law that would be seen as a barrier to adopting e-prescribing and HIT technology.

PROVISIONS OF THE PROPOSED REGULATIONS
C. Proposed Requirements for Part D Plans

The AOA questions why closed networks would be exempt from the standards. Allowing such an exemption would contradict the universality of protocol adoption. If a closed network must convert from HL7 to NCPDP SCRIPT to communicate prescriptions to community and retail pharmacies, as well as be able to receive prescription transmittals via NCPDP SCRIPT from outside enterprises, then wouldn't it be appropriate to use NCPDP SCRIPT inside the network as well?

In addition, allowing such an exception to the rule will only complicate the following of other rules. Under HIPAA, the transaction requirements apply to both closed and open environments. Since both rules are encompassed around patient information, consistency would be favorable.

E. Proposed Standards

The AOA found an inconsistency in the Proposed Rule regarding the Prescription Fill Status Notification Transaction. According to the preamble on pg. 6265, the Prescription Fill Status Notification Transaction and its three business cases are excluded from the foundation standards due to inadequate industry experience. However, on page 6266, it states "the NCPDP SCRIPT Standard transactions we propose for adoption have been used extensively for messaging between prescribers and retail pharmacies for new prescriptions, prescription refill requests, **prescription fill status notifications** and cancellation notifications, as part of the Consolidated Health Informatics Initiative." We would appreciate a clarification on whether industry experience exists.

If the first statement is correct and there is no significant industry experience in the area of Fill Status Notification Transaction, then it should in turn be part of a pilot project to gain the experience. A Fill Status Notification could serve as a quality tool for physicians. Many patients are non-compliant with physician recommendations, including prescriptions. Having the mechanism of viewing when and if a prescription is filled can play a major role in the quality of care that the patient receives.

IMPACT ANALYSIS
C. Impact on Prescribers

While the AOA believes that e-prescribing is a helpful tool in improving the quality of patient care and increasing efficiency, primary care physicians who oversee the care and medication provided to their patients by other physicians plays a greater role in significantly reducing the potential problems of overmedication, under-medication, and/or harmful drug interactions.

In addition, having only osteopathic and allopathic physicians prescribe or supervise prescriptions written by non-physicians clinicians is important step in significantly reducing the problems of inappropriate drug use and/or harmful drug interactions. The AOA supports shared responsibility among patients, caregivers, and physicians to ensure appropriate drug use.

CMS and stakeholders must be cautious in their expectations regarding e-prescribing. A U.S. Pharmacopeia study found that medication errors attributable to computerized prescribing are increasing. E-prescribing mistakes accounted for almost 20% of all hospital and health system medication errors in 2003. "Computer entry errors were the fourth leading cause of medication errors in U.S. hospitals and health systems," according to USP.

CONCLUSION
Putting Patients First—Patient Centered Quality Care is the AOA's theme. We believe that one of the fundamental principles of patient centered quality care is the ability of patients in our care to have access to appropriate drug therapies. We realize controlling costs is an important factor, however, access to appropriate treatments must be the primary focus. Promoting the use of cheaper drugs could prevent the selection of appropriate treatment protocols, which directly affects the patient's health. We hope that as CMS develops its policies on e-prescribing, the main focus will be ensuring access to appropriate treatments while improving the quality of patient care and safety.

***

The AOA appreciates the opportunity to comment on the proposed e-prescribing rule. We look forward to working with CMS in the future on this and other issues of concern to the osteopathic medical profession. If you have any questions, please contact Kelly Lavin, AOA Regulatory Analyst, at 202-414-0140.

Sincerely,

George Thomas DO

George Thomas, DO
AOA President

CC: President-Elect, AOA
Members, Board of Trustees, AOA
Chairman, Department of Government Affairs, AOA
Chairman and Members, Council on Federal Health Programs, AOA
Executive Director, AOA

**Submitter :** **Bruce Kelly** **Date:** **04/04/2005**

**Organization :** **Mayo Clinic**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

**Issues**

Provisions of the Proposed Regulation

See attachment

CMS-0011-P-17-Attach-1.DOC

MAYO FOUNDATION

**Mayo Foundation**
1025 Connecticut avenue NW, Suite 1012
Washington DC, 20036
202-327-5424 Fax: 202-327-5426

**Office of Government Relations**

April 4, 2005

Centers for Medicare and Medicaid Services

Re: CMS-0011-P
Medicare Program: E-Prescribing and the Prescription Drug Program

On behalf of Mayo Clinic I am submitting comments in response to the notice of proposed rulemaking cited above.

Mayo Clinic is a multi-specialty group practice with major sites in Rochester, Minnesota, Jacksonville, Florida, and Scottsdale and Phoenix, Arizona. We see patients from all over the country at each of our sites, and accordingly our comments will focus primarily on the ramifications of the rule on a large, national, multi-specialty academic health center.

Mayo supports the movement toward broad use of electronic transactions in healthcare. We have moved within our own institution to an electronic medical record, and we believe the widespread use of better electronic records and information technology is absolutely necessary for the future of healthcare. We also support the concept of interoperability to allow electronic communications among different systems in a seamless manner.

The proposed rule establishes several basic standards to be adopted for the Medicare electronic prescribing system, and we support the adoption of these standards, which were developed through a consensus process. Our comments will focus on the broader issues raised in the NPRM of how the electronic prescribing system will evolve and the appropriate roles within that system for the various parties involved.

We believe the model for the system needs to be built with the patient and the patient's physician or other prescribing healthcare professional (prescriber) at the center. This is the point where issues of medical appropriateness, patient medical and medication history, drug interactions, and allergies are dealt with and resolved. It is also the opportunity for the prescriber, with the patient present, to make decisions about possible generic substitution and the necessity of using off-formulary drugs in the individual case. Therefore, this should be the starting point for the electronic system. If the prescriber has covered all these issues with the patient, the need for interventions downstream will be obviated. The system should be built around this patient-prescriber focal point. The prescriber should have access at this point to whatever information is available through the PBM, rather than having the PBM be the focal point for information after the medication has already been prescribed. In addition, the information exchange between the prescriber and PBM must be limited to the information necessary to make appropriate medical and cost effectiveness decisions, without the insertion of any messages that could be construed as the marketing of a particular drug.

The patient-prescriber focal point model will require a system that is user friendly, and one that practitioners will be willing to embrace. It must be pilot tested for not only technical functionality, but also ease of use, effectiveness of communications, time required to complete the prescribing process, and potential problems of information handoffs from prescriber to PBM and pharmacy. The model must make the prescriber's job easier, and be seamless to the patient. The process must also eliminate repetitive flagging of the same issue after the prescriber has signed off on a prescription. The prescriber and patient should have to deal only once with these flagged issues.

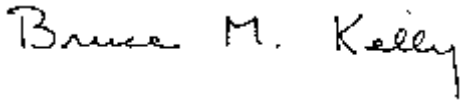
In the case of centers such as Mayo Clinic, the system must also be nationwide. We will likely see Medicare patients enrolled in every drug plan in the nation. The ability to deal efficiently with all plans will be a necessity, with the same criteria needed as described above. This will require uniformity of systems to access information among the drug plans. For example, standardized models will be required for patients and prescribers to navigate formularies and access other information held by different PBMs.

In order to achieve the objectives we have outlined, we strongly urge that this system be developed incrementally, with pilot testing of all elements. While technical standards may seem straightforward in theory, or even in local settings with a limited number of parties involved, in the real world of mobile patients and multi-state providers, plans, and pharmacies, there is huge potential for unintended consequences. The pilot testing is needed to assure that standards are both technically and practically (in a real clinical setting) useful and efficient. What will make or break this system are not necessarily the standards themselves, but the ability to have workable procedures and policies to make effective use of the standards. Many details need to be addressed, such as which issues will trigger alerts, how those alerts will be displayed, how workflow will be affected, who will maintain and update medication and allergy lists, how will organ dysfunction be captured, and many other critical questions. Reality testing will be crucial for achieving a workable system.

We also urge your attention to making sure this system is compatible with electronic patient records already being used by many hospitals and medical groups (including Mayo Clinic). We already are dealing with an electronic environment, and this new system should not be constructed outside of the existing electronic world. Focus should be on use of existing data standards to insure interoperability and portability of this type of information. The system should also be constructed with HIPAA privacy concerns built into the model. With patient drug information, and eventually medical history, being housed in this system, it will be imperative to protect patient privacy.

Thank you for your consideration of these comments. For further information I can be reached at 202-327-5424.

Sincerely,



Bruce M. Kelly
Director of Government Relations
Mayo Clinic

**Submitter :** **David McLean, PhD** **Date:** **04/04/2005**

**Organization :** **RxHub**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-18-Attach-1.DOC

RXHUB™
Where the Prescribing Industry Connects

April 4, 2005

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

*Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program Notice of Proposed Rule Making (NPRM) [42-CFR Part 423] – Comments*

Dear Madams / Sirs:

RxHub is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

At a time when society is focused on a rise in medication errors, increasing costs, and the need to provide benefit to our seniors and most needy, electronic prescribing holds the most promise for relief. RxHub was founded in 2001 by the three largest pharmacy benefit managers (PBMs) to advance the acceleration of electronic prescribing—electronically delivering real-time access to patient medication history and formulary and benefit information at the point of care. We have learned that electronic connectivity between payers, physicians, and pharmacies is essential to improving patient safety and containing health care costs. We have successfully demonstrated this through:

- building a secure, private connectivity infrastructure able to handle high transaction volume,
- building an open, standard means to share prescription drug benefit information with all participants in the prescription delivery team,
- facilitating the adoption of open, uniform standards, and
- forging industry-wide alliances and participation.

Today, clinicians use this information to make more informed and safer prescribing decisions, reducing medication errors at every point of care. We are working with over 40 participants (and growing), generating over 1 million transactions per month, demonstrating more than adequate industry use and acceptance. Each one of these transactions represents a patient visit with one or more possible prescriptions.

RxHub strongly supports the development of standards for electronic prescribing, and we have actively participated in the process of the National Committee for Vital Health Statistics (NCVHS) leading up to the release of the NPRM. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to the passage of the Medicare prescription drug bill, and we believe Congress intended to achieve true standardization of electronic prescribing for the benefit of the nation's health care.

## BACKGROUND

**Commenting on: Statutory Basis- Definition of Electronic Media (F. R. page 6257)**

*According to the NPRM, "Electronic media" means:*

*(1) Electronic storage media, including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or*

*(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission."*

**RxHub Recommendation:**

This rule seems to include (but does not specifically mention) **electronic faxes**, since those transmissions were created in an electronic format, then transmitted electronically. Since electronic faxes are electronic media, they could also considered electronic prescriptions, per the interpretation of the definition on page 6273 of the NPRM (section 423.159):

> *E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.*

Electronic faxes are computer generated files transmitted by fax that never exist in non-electronic form and thus do not fall within the exception set forth in the last sentence of HIPAA's definition of "electronic media." However, electronic faxes do not comply with the proposed standards, as they do not utilize the NCPDP Script standard, and could not be used to e-prescribe under the NPRM as currently drafted. Furthermore, electronic fax software does not support the communication of eligibility or formulary and benefit information, which e-prescribers are required to support.

RxHub would recommend that given the number of entities currently utilizing electronic faxes, and given an accelerated timeframe for implementing the e-prescribing program under MMA, that HHS may want to include a transition period in the Interim Rule during which those entities could continue to utilize electronic faxes for the electronic transmission of prescribing information.

**Commenting on the following Sections:**

**I. A. Background/Statutory Basis (F. R. page 6257**
**I. F. Background/Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)**
**II. Provisions for the Proposed Regulation (F.R. page 6265)**

**Also relates to I. H. Background/Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. page 6264)**

**RxHub Recommendation:**

**Standards Approval Should Not be Dependent upon ANSI Accreditation**

For the development and implementation of standards under the e-prescribing program, the NPRM offers for comment three criteria to give meaning to the statutory requirement that a candidate standard have "adequate industry experience." These criteria are: 1) the standard is American National Standards Institute (ANSI) accredited; 2) the standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner (demonstrated interoperability); 3) the standard is recognized by key industry stakeholders as the industry standard (no competing standards to cause potential confusion). There is no indication in the NPRM that these criteria are to be considered in the alternative or cumulatively. Moreover, there is a confusing subsequent paragraph in the section implying that ANSI accreditation criterion is the sole criterion in determining whether a candidate standard met the requirement of "adequate industry experience." The NPRM asserts on page 6261 that "[t]he standards [for electronic prescribing] should be vendor neutral and technology independent, and developed by Standards Development Organizations (SDOs) that are accredited by the ANSI."[1]

While we support the goal of leveraging the capabilities, experience, and broad industry participation of ANSI-accredited organizations in the quest for identifying standards, we are also concerned about including ANSI accreditation as a threshold requirement. To the extent the NPRM is intending to require that any standard, whether it is a "foundation[2]," initial or future standard, be ANSI accredited before it can be approved, we oppose such a requirement. We support the position that a candidate standard may be approved in HHS' discretion if it has been implemented by "entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner" and the standard "is recognized by key industry stakeholders as the industry standard," even if it has not been accredited by ANSI or an ANSI accredited organization. Our position is consistent with Congress' express intent in MMA.

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[1] We also note that the NPRM (p. 6261) identifies as the first criterion for determining "adequate industry experience" that the "the standard is American National Standards Institute (ANSI) accredited." Note that the September 2, 2004 NCVHS recommendation letter to the Secretary of HHS stated as "guiding principles for selecting standards" (p. 4) that standards "should be vendor neutral and technology independent, preferably be developed by standards development organizations accredited by the American National Standards Institute (ANSI), and have suitable indications of market acceptance." (emphasis added) We assume the NPRM's reference to ANSI includes organizations that are recognized by ANSI, as set forth in the NCVHS recommendation.

[2] The NPRM defines on page 6261 "foundation" standards as standards that do not need to be pilot tested because adequate industry experience with those standards already exists.

**Congress Mandated Standard Setting Responsibility be Retained by HHS**

Congress mandated that the process to follow in approving standards for the e-prescribing program does not consist of ANSI accreditation as the sole determinant. The basis for Congress' intent to have a broader set of criteria utilized is because there is no standards development organization today that has representative participation from all the requisite industry stakeholders. To give great clarity on this important point and the need for a broader process, MMA specifically requires that all industry stakeholders as enumerated in the statute need to participate in the standard-setting process. MMA appoints NCVHS to play a primary role under the oversight of HHS, which is to retain discretion for the e-prescribing program both for "initial" standards and as the standards evolve under the e-prescribing program. It also identifies the requisite stakeholders with whom NCVHS should consult in developing initial standards as follows: 1) standard setting organizations; 2) practicing physicians; 3) hospitals; 4) pharmacies; 5) practicing pharmacists; 6) pharmacy benefit managers; 7) state boards of pharmacy; 8) state boards of medicine; 9) experts on electronic prescribing; and 10) other appropriate Federal agencies. Section 1860D-4(e)(4)(B). MMA provides for consulting with standard setting organizations, of which NCPDP is one, as well as the other requisite stakeholders, but does not defer overall approval for standards to such an organization.

Relying on industry standard setting organizations creates a risk that parties with particular agendas or ulterior motives can usurp the process, preventing any standard from getting passed, despite broad consensus and/or the lack of any alternative standard for a given transaction type. NCPDP traditionally has enjoyed significant participation from the pharmacy stakeholders. The physician community, critical to the success of the e-prescribing program, is a primary example of a group historically without significant participation in NCPDP. As the e-prescribing program and other emerging e-health initiatives continue, there may be other bodies including standards setting organizations that will organize in the near term with relevant expertise and experience with whom HHS would be well-served to consult for standards approval. In addition, standards may meet the requirements of implementation and stakeholder recognition through means other than an ANSI accreditation process. [1]

The legislative history evidences Congress' intent on the issue of managing the approval of standards. The House–passed bill contained language providing that the standards under the e-prescribing program be issued by a standards organization accredited by ANSI.[2] However, this specific provision was removed during conference, and the final version of the enacted statute did not retain this requirement. This is strong evidence of Congress' preference that HHS receive the input of not only ANSI accredited organizations but all stakeholders, including those not currently represented by such bodies. As a result, the role of NCVHS working in conjunction with HHS to ensure that the process includes all industry stakeholders (identified in MMA) and be conducted in a neutral manner and in a time frame required by MMA, is clearly intended by Congress. For the NPRM to establish requirements that include an ANSI certification as a stand-alone requirement is contrary to what Congress specified in MMA and risks that standards will not be available within the set time frames or that useful and otherwise valuable standards will be by-passed.

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[2] H.R. 1.EH, The "Medicare Prescription Drug and Modernization Act" passed by the House on June 27, 2003. See Section 1860D-3(d)(3)(B)(iii)(III).

In addition, the ANSI accreditation process is, as acknowledged by the NPRM, a time consuming process and if there is a requirement that such accreditation occur before a standard is adopted, there is the risk of substantial delay, which contradicts the express will of Congress as reflected in the deadlines set forth in MMA and the NPRM's own even more ambitious timeline.

Moreover, if a standard meets the second and third criteria, it can still become ANSI accredited, but HHS does not need to wait for such a final decision. If for any reason there is a different or updated standard that comes out of the ANSI accreditation process after adoption of a standard, HHS is free to incorporate such a result in light of its standard setting process.

We recommend that HHS not implement a requirement that all standards (foundation, initial or future) be certified by an ANSI accreditation consistent with the requirements of MMA. HHS should be the final arbiter of the standard-setting process to ensure that all industry stakeholders are adequately represented, that the process remains neutral and expeditious, that the statutory deadlines are met, and appropriate future standards are promulgated in a timely fashion.

**Support for Adoption of RxHub Protocols as Foundation Standards Under Two Criteria**

As an example, of standards that do not need to go through the ANSI accreditation process, we point to the RxHub protocols (the Protocols[1]) for formulary / benefits information and for medication history to be adopted as foundation standards. The Protocols meet criteria two and three set forth in the NPRM, and each of these criteria provide sufficient evidence to satisfy the requirement that there be adequate industry experience. The Protocols are in wide use today, after being developed in the spirit of other standard-setting organizations giving credence to an open, consensus-building process to multiple stakeholders and working to improve existing standards.

The Protocols were developed after the company was formed in 2001 through an open, public workgroup process that it facilitated in several U.S. cities. RxHub sought the consensus of stakeholders including technology vendors, PBMs, health plans, pharmacies, pharmaceutical manufacturers, hospitals and other routing companies. RxHub began with existing standards already being utilized in the industry. RxHub published the proposed standards on the Internet with an open public comment period to obtain feedback from the industry. Production pilots were performed starting in 2002 to test the standards, including applicability to physician office and technology vendor application workflow. RxHub's standards have been modified as experience has been gained. RxHub standards are in broad use today, including: thirty-three partners use the transactions in production applications; five additional partners are certified, ready for production; five additional partners are currently certifying on RxHub transactions; and others are developing to RxHub specifications. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing process further validates the conclusion that the Protocols meet the two criteria demonstrating adequate industry experience, resulting in approval as foundation standards.

RxHub has submitted the Protocols to NCPDP for accreditation. NCPDP accreditation includes an extensive and time consuming process. The time to achieve NCPDP accreditation for a proposed new standard can take a year or more. The NPRM clearly recognizes that this is a complex, time consuming process. As the Protocols clearly satisfy criteria two and three evidencing "adequate industry experience," it serves as a prime example of why ANSI certification should not be required for approval as foundation standards. Obviously, the e-prescribing program can nevertheless incorporate standards developed through the ANSI accredited standard setting process.

**Commenting on:**
**Background: Statuary Basis/ State Preemption (F.R. page 6259)**
**Provisions: H. Effects on States and Federalism Statement (F.R. Page 6272)**

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenter believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**RxHub Recommendation:**
We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, predictable, national scheme, physicians and pharmacist will be uncertain as to their obligations which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic software technology vendor, with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available.

CMS stated in the preamble to the NPRM that "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of state law that will require detailed analysis in all 50 states to figure out how existing state law should be read to mingle with federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a state requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that state require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?

- Does a Medicare prescription transmitted electronically need to meet state rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable state forbids such intermediaries?
- Can the physician or pharmacist be disciplined under state law where a prescription is sent electronically according to the federal rule but it is deficient for state law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer) which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of all this confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

We believe a single, national set of standards for electronic prescribing are in the interest of all parties, including the states. The principal concern of states would not likely be that the federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that state boards of pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the state boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- rules relating to formatting of prescriptions and documentation of the prescriber's intent
- rules relating to authentication of the prescriber
- rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of standards applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of federal and state laws affecting all electronic prescriptions. The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant state law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon the proposed approach of taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as federal standards are adopted for electronic prescriptions, they preempt any contrary state standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules

addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all state rules on those topics with respect to all electronic prescriptions.

**Commenting on: Evolving and Standard Setting Process (F.R. page 6261)**

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**RxHub Recommendation:**
In terms of addressing future standards under the e-prescribing program, there are two important issues raised under the NPRM: 1) whether to configure at this point in time a predetermined formula for all standards that may be proposed in the future; and 2) whether all future standards will be approved if they meet a single criterion, ANSI accreditation.

We are concerned about the issues identified in the foundation standard-setting process as they apply to future standards and ask for restraint from imposing at this time a detailed regulatory process for future standards that may be precise in process but short-sighted in consequence. HHS already is empowered to issue guidance from time to time as necessary as it gains experience with the issues and oversees the e-prescribing program's implementation. It should not impose at this point in time an ANSI accredited standard setting process as the sole requirement for approval, particularly given the need for broader consensus building, neutrality and participation by all industry stakeholders.

Accordingly, we recommend that HHS not issue a predetermined formula to approve future standards until and unless needs for this are clearly identified beyond a successful implementation of the foundation and remaining initial standards.

As needs for future or evolving standards become clear, HHS is authorized to provide guidance from time to time on an ongoing basis. Such guidance may address matters related to the standards that remain within the scope of MMA and impact the maintenance of "backward compatibility" among e-prescribing program participants.

**Commenting on: G. Electronic Prescription Drug Program (F.R. page 6261)**

*Two of the eight Administrative Simplification Standard Transactions conducted between providers and health plans at §162.1101 through §162.1802 (the NCPDP Telecommunication Standard for Health Care Claims, and the ASC X12N 270/271 Eligibility Inquiry and Response Standard for eligibility for a health plan queries), are proposed in this rule for e-prescribing foundation standards. The NCPDP Telecommunication Standard is proposed for eligibility inquiries and responses between pharmacies and health plans, and the ASC X12N 270/271 is proposed for eligibility inquiries between prescribers and health plans. The standards must be designated to enable transmission of basic prescription data to and from prescribers and dispensers, a well as the transmission of information about the patient's drug utilization history, possible drug interactions, the drug plan and cost information.*

**RxHub Recommendation:**
RxHub supports the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers. This

transaction set supports real-time mode lookup, sending a request to the appropriate benefits administrator for additional information and including the patient's Cardholder information as well as links to the benefit information for accessing formulary and benefit information, medication history and processing the drug claim. In addition, this standard transaction set can support COB by informing the prescriber that the individual is covered under multiple plans.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patent's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction be piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

RxHub notes that eligibility request and response transactions can be used with information source organizations other than health plans (i.e., for transactions that are not standard transactions as defined by HIPAA). *See, e.g.,* ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, Page 11, Section 1.3.1. Consequently, RxHub recommends that CMS define the two eligibility transactions for which it proposes standards as "eligibility inquiries and responses submitted and received by pharmacies" and "eligibility inquiries and responses submitted and received by prescribers". This would not change the fact that a provider that is not otherwise a covered entity under HIPAA would become a covered entity if it conducts an e-prescribing transaction that is also a HIPAA standard transaction, such as exchanging 270/271 eligibility and response transactions with a health plan.

**Commenting on: Table of transactions (F.R. page 6262).**

*The key NCVHS recommendations concerning functions related to interoperable electronic exchange of information and whether they are included in the NPRM are summarized in the table page 6262.*

**RxHub Recommendation:**
Remove function titled "Exchange of medication history, and medical history for e-prescribing program" from the table as this is covered in two distinct functions one of which is currently being addressed: Medication History and the other which will be subject to future NCVHS hearings: Medical History.

**Commenting on: Provider and Dispenser Identifiers (F.R. page 6263)**

*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**RxHub Recommendation:**

Currently, RxHub supports the use of the NCPDP Provider ID for pharmacy providers and the DEA number for physicians. We also create a unique ID for each physician/location/Point of Care vendor combination. RxHub plans to support use of the NPI once it becomes available. However, there will need to be a transition period in order to move to the industry's use of the NPI while the industry is still supporting other identifiers. RxHub supports and encourages the use of pilot projects using the NPI in 2006. Adoption of NPI in e-prescribing program should not be required until May 2007 deadline, only if there is adequate industry experience in the use of the NPI and acceptable business practices are available for distribution of the NPI file to the industry. Until that time, the current identifiers should be supported.

We recommend that the Interim Rule affirms that HHS intends to require the use of approved identifiers for use by entities participating in the e-prescribing program in the Final Rule upon completion of the pilot tests and that it authorizes the use of current identifiers until the Final Rule is issued

**Commenting on: Provider and Dispenser Identifiers (F.R. page 6263)**

*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

**RxHub Recommendation:**
RxHub and the industry currently support the use of the NCPDP Provider ID for identifying dispensers. We would support the use of NCPDP HCIdea for identifying prescribers if the industry moves in that direction. It is important that the same identifiers be used for both Medicare and non-Medicare prescriptions.

**Commenting on: Formulary and Benefit Coverage Information and Medication History Standards (F.R. page 6263)**

*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards*

**RxHub Recommendation:**
The e-prescribing industry has sufficient experience with the standards currently being used by RxHub and its many partners for formulary and benefits information and medication history to be named as foundation standards. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing industry, clearly demonstrate adequate industry experience with the RxHub standards for formulary and benefits information and medication History. RxHub has submitted these standards to NCPDP to be worked through the approval process for becoming ANSI-accredited standards. There have not been significant changes made to the submitted formats and therefore these standards should be named as foundation standards which will not cause additional rework on behalf of those entities already utilizing these formats in their current e-prescribing transactions.

The Medication history standard is currently being balloted with the NCPDP membership, and the formulary and benefits information standard has been submitted to NCPDP and upon approval will be taken to ballot. RxHub anticipates that these standards will be approved but the outstanding question is timing of the final accreditation.

We support adoption of the RxHub standards for communication of formulary and benefits information and medication history information between health plans / PBMs and physicians via their technology vendors. We believe these should be adopted in the final rule as final standards. We do not believe it is necessary for these standards to be validated by an ANSI-accredited organization, given that the participants in the industry that are doing electronic prescribing have effectively adopted these as their "de-facto" standards for communication of this type of information, and that the industry has extensive experience in the use of these standards. The vast majority of electronic prescribing solution providers and each of the three largest PBMs (representing over 150 million lives) are using these transaction sets today and have been for several years.

**Commenting on: Drug Information (F.R. Page 6264)**

*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.* (SPL discussion)

**RxHub Recommendation:**
RxHub plans to support new drug information standards as they are approved and become available.

**Commenting on: H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)**

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*
*• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*
*• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*
*• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

**RxHub Recommendation:**
RxHub supports naming NCPDP SCRIPT and ASC X12N 270 / 271 as these foundation standards. Minimum standard is what is indicated in the NPRM as the "floor" with the assumption that higher versions are acceptable.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patent's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction is piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

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**Commenting on: Standards for Interoperability (F.R. Page 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**RxHub Recommendation:**
Standards for e-prescribing and EHRs can be implemented independently, as there is no value to curtailing the momentum that is already building in the industry today around e-prescribing. EHRs are very broad reaching and may be implemented at different times or addressing different business cases. RxHub considers e-prescribing as a vital component of the EHR application. E-prescribing is available today and is being used. We support addressing interoperability between different standards in order to more easily integrate healthcare applications and functionality. Future features and functions should be incorporated into the whole continuum of care, but it is our strong recommendation not to postpone what is available and in use today

## II. PROVISIONS

**Commenting on: C. Proposed Requirements for Part D Plans (F.R. Page 6265)**

*The Medicare Prescription Drug Benefit final rule has specific language that requires Part D sponsors to support and comply with electronic prescription drug program standards relating to covered Part D drugs, for Part D enrolled individuals once final standards are effective. Effective January 1, 2006, Part D sponsors would be required to have an electronic prescription drug program and would be required to support electronic prescribing, once standards are in place.*

**RxHub Recommendation:**
RxHub agrees and supports the recommendations from NCVHS.

**Commenting on: (F.R. Page 6265)**

*We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.*

**RxHub Recommendation:**
RxHub agrees with the recommendations from NCVHS.

**Commenting on: E. Proposed Standards (F.R. Page 6265)**

*We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

**RxHub Recommendation:**
RxHub agrees with the conclusion as recommended by NCVHS to not adopt these at this time due to inadequate industry experience and business case use.

**Commenting on: (F.R. Page 6265)**

*We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:*
*• New prescription transaction*
*• Prescription refill request and response transactions*
*• Prescription change request and response transactions*
*• Cancel prescription request and response transactions*
*• The following ancillary messaging and administrative transactions:*
*+Get message transaction*
*+Status response transaction*
*+Error response transaction*
*+Verification transaction*
*+Password change transaction*

**RxHub Recommendation:**
RxHub agrees with the naming of NCPDP SCRIPT as a foundation standard, however, not all messages in the information exchange have been proven to have adequate industry experience. In addition, not all messages (e.g. Get message and Password Change) are required in all business models. Therefore we agree with naming all messages within the SCRIPT Standard, but not requiring all messages to be supported.

**Commenting on: 2. Eligibility (F.R. Page 6266)**

*We are proposing, at new §423.160(b) (2) (i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*
*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*
*We are proposing to adopt, at proposed §423.160(b) (2) (ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

**RxHub Recommendation:**
RxHub supports naming NPDPD SCRIPT and X12 270/271 as foundation standards.

Based on RxHub's research on the use of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the pharmacy to payer; RxHub believes that there is not much (if any) industry experience in using the E1 message. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patent's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not currently being used for this purpose, we recommend it be excluded from the final rule. At a minimum RxHub recommends that this transaction is piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

## IV. REGULATORY IMPACT ANALYSIS

**Commenting on: Prescriber Participation Expectations (F.R. Page 6268)**

*We invite public comment on our expectations for prescriber participation*

**RxHub Recommendation:**
Please see RxHub's response at *I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259).*
There is a consistent and growing body of knowledge about the factors that, until now, have impeded the emergence of e-prescribing on a nationwide basis. One major factor is the reluctance of physicians to adopt new e-prescribing technologies.[1]

One way to overcome physician inertia is to provide incentives for them to adopt the new electronic technologies needed for e-prescribing. This is a mandate on HHS as a part of President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335, issued April 27, 2004.

It could be cost-effective for some plans or pharmacy benefit managers to provide electronic devices and software to physicians without charge as an incentive to encourage their adoption of e-prescribing practices. The NPRM notes (p. 6270) that, "One of the barriers to early adoption of e-prescribing by prescribers is the cost of buying and installing a system….Since these costs may be defrayed by the incentives that are being offered, we expect a steady increase in the number [of] electronic prescribers."

The NPRM makes clear (p. 6269) that pharmacy plans and pharmacy benefit managers are likely to find it cost-effective to provide incentives to encourage e-prescribing: "We expect many plans to provide these incentives [i.e., financial incentives and technical assistance] to prescribers to offset the prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing."

[1] "In health care, the average investment in information technology computer hardware, software, and services is only about $ 3,000 annually for each worker, compared with $ 7,000 a worker on average for private industry and nearly $ 15,000 a worker in banking….But health care remains a fragmented industry, with much of the care still provided by physicians in small practices." Steve Lohr, "Health Industry Under Pressure to Computerize," *New York Times*, February 19, 2005.

As the NPRM also points out, a major impediment to the provision of these needed incentives is the existence of federal and state laws prohibiting kickbacks and physician self-referrals. The NPRM states that HHS will address these impediments by issuing a proposed rule to create an exception under Section 1877 of the Act (the "Stark law") for incentives relating to e-prescribing and that the department's Inspector General is considering how best to establish a safe harbor under the federal Anti-Kickback statute.

The Government Accountability Office points out that state law is prevalent in this field: "Many states have laws analogous to the federal self-referral and anti-kickback laws, some of which are stricter or have fewer exceptions, or both."[1] However, the proposed rule fails to preempt or otherwise address these conflicting and burdensome state laws.

**Commenting on: A. Overall Costs & Savings Impact (F.R. Page 6268)**

*We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.*

**RxHub Recommendation:**

Americans made more than 823 million visits to physicians' offices in 2000[2] and according to the National Association of Chain Drug Stores (NACDS); four out of five patients who visit a doctor leave with at least on prescription.[3] Close to 4 billion prescriptions will be written in 2006, as prescription medications are used by over 65 percent of the U.S. population in a given year.[4] It is our opinion that with this significant volume, even a small improvement in quality attributable to electronic prescribing would translate into significant healthcare cost savings--and hospitals, pharmacies, health plans and purchasers all stand to gain form an accelerated adoption of this technology. RxHub delivers via its industry adopted "de-facto" standards relevant patient information and clinical knowledge to the prescriber, thus reducing the likelihood of a medication error. This change in approach represents a fundamental overhaul to our national prescription error prevention system, and the safety implications are staggering: CITL estimates that nationwide adoption of electronic prescribing will eliminate nearly 2.1 million adverse drug events annually in the United States.[5] This same study projected a savings of $27 billion annually with widespread adoption of electronic prescribing

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[1] Government Accountability Office, *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, GAO-04-991R, August 13, 2004, p. 47.

[2] Pastor PN et. Al. Chartbook on trends in the health of Americans. Health, United States, 2002. National Center for Health Statistics. 2002

[3] The chain pharmacy industry profile. National Association of Chain Drug Stores. 2001

[4] Agency for Healthcare Research and Quality. MEPS Highlights #11: distribution of health care expenses, 1999.

[5] Center for Information Technology Leadership. The value of computerized provider order entry in ambulatory settings, 2003. This study also reported that over 8.8 million adverse drug events (ADEs) occur each year in ambulatory care, of which more than 3 million are preventable. The widespread adoption of e-prescribing would prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 ADEs annually.

**Commenting on: B. Impact on Health Plans/PBMs Cost & Financial Benefit (F.R. Page 6269)**

*We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans.*

**RxHub Recommendation:**
Cost or, perhaps more accurately, a lack of documented cost / benefit analysis, has been one of the primary barriers to adoption thus far. Furthermore, there are costs involved in supporting electronic prescribing that the industry may not be prepared to absorb, transaction fees in particular.

It is important to distinguish the costs associated with supporting electronic prescribing functionality according to the standards to be adopted from the transaction costs associated with conducting electronic prescribing. While some of the larger PBMs have implemented electronic prescribing capabilities and have historically supported the transaction fees associated with providing formulary and benefit information for electronic prescribing, it isn't clear, particularly given how the PBM market is evolving, that payment of these fees by PBMs can or will continue, and there is a lack of precedent for other parties in the chain paying these fees directly. The market will have to sort out where the value from electronic prescribing accrues, and allocate fees accordingly. It will be important for the anticipated pilot tests to carefully measure where and to what extent value accrues from electronic prescribing, in order to better inform the market as to how these costs should be allocated.

One way to reduce the costs associated with providing electronic prescribing technologies to the market will be to implement a single, national set of standards for all electronic prescribing, so that technology vendors do not have to incur inordinate expense in researching and keeping up-to-date on the evolving federal and state regulatory schemes, and developing systems to comply in each jurisdiction in which they operate.

**Commenting on: D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)**

*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**RxHub Recommendation**
It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new versions of the standards must be predictable and timely (in industry time speed) to not negatively impact the movement of the industry to new business functions and needs.

**Commenting on: E. Impact on Patients (F.R. Page 6271)**

**RxHub Recommendation:**
We agree that the impact of electronic prescribing will have a positive influence on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance. E-prescribing with the development of common standards and streamlined communication between physicians, patients and pharmacy will encourage accelerated adoption based on the value proposition that will be demonstrated. Patients will have the added ability to

take a more proactive approach and responsibility for the health care they receive. Electronic prescribing practices will enable patient's to track their medication use to assist in efforts to improve compliance and also allow physicians to monitor risk of abuse by prescriptions obtained through multiple providers and pharmacies.

**Commenting on: F. Impact on Technology Vendors & Others (F.R. Page 6271)**

*We have no estimates for these types of costs and invite public comment from healthcare information technology vendors and others on the impact of e-prescribing.*

**RxHub Recommendation:**
It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. There is a healthy competition and advancement of the industry today as a result of the requirements stated in the MMA. The process of migrating to new versions of the standards must be predictable and timely (in industry time speed) to not negatively impact the movement of the industry to new business functions and needs.

**Commenting on: (F.R. Page 6273)**

*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*

**RxHub Recommendation:**
RxHub supports the adopting the formulary and benefit standard and medication history standards as a functional equivalent standard in the final rule and we encourage the piloting of these standards to continue demonstrating and validating what is currently successfully implemented in the marketplace today.

**CONCLUSION**
RxHub has built a national network that connects all the key stakeholders in the medication prescribing process which includes physicians, pharmacies and payers, thus playing a key role in improving the lives of patients and lowering costs for everyone concerned. Our leadership and success at forging participation and industry alliances has facilitated the development of standards where none existed and the promotion of standards already in industry use.
Functioning as the definitive "national exchange network" for electronic prescriptions—from delivery of relevant information at the point of prescribing for informed decision making through the transmission of the prescription electronically to the pharmacy of patient's choice; has significantly impacted physician adoption.
RxHub will continue to support and assist CMS in the acceleration of adoption in the use of health information technology to achieve better quality outcomes, improved efficiency and reduction on overall healthcare costs.

Sincerely,

David McLean, PhD
CEO
RxHub
380 St. Peter Street, Suite 530
St. Paul, Minnesota 55102
651-855-3000
dave.mclean@rxhub.net

**Submitter :** **Mr. David Karmol** **Date: 04/04/2005**

**Organization :** **American National Standards Institute (ANSI)**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

SEE ATTACHMENT

CMS-0011-P-19-Attach-1.DOC

File Code: **CMS-0011-P**

42 CFR Part 423

**Medicare Program: E-Prescribing and the Prescription Drug Program**

AGENCY: Centers for Medicare & Medicaid Services (CMS) HHS

Comments of the American National Standards Institute (ANSI)
www.ansi.org
1819 L Street NW
Washington DC 20036

Contact:
David L. Karmol
Vice President, Public Policy & Government Affairs
dkarmol@ansi.org
202-331-3610

Our submission is divided into two parts, preliminary remarks designed to frame our comments, and comments on the proposed rule itself.

**1. PRELIMINARY REMARKS: Description of the U.S. voluntary standards system and the role of the American National Standards Institute (ANSI)**

With respect to this proposed rule, the Congress specifically recognized the value of using standards from ANSI-accredited standards developers when it passed the Health Insurance Portability and Accountability Act of 1995. At Sec. 1171(80), Congress chose to define a Standards Setting Organization as one that is accredited by the American National Standards Institute. This recognition and acknowledgement is reflected in the proposed rule.

In the healthcare sector, the American National Standards Institute's Healthcare Informatics Standards Board (ANSI HISB) provides an open, public forum for the voluntary coordination of healthcare informatics standards among all United States standard developing organizations. Every major developer of healthcare informatics standards in the United States participates in ANSI HISB. The ANSI HISB has 27 voting members and more than 100 participants, including ANSI-accredited and other standards developing organizations, professional societies, trade associations, private companies, federal agencies and others.

Because we find that the standardization system, and its terminology, remains a mysterious and sometimes confusing realm, we begin our submission

with the following introductory remarks to provide a basic description of the system that produces standards, and the role that ANSI plays in the system.

The voluntary standardization system in the United States is the most effective and efficient in the world. For almost 100 years, this system has been administered and coordinated by the private sector through ANSI, with the cooperation of federal, state and local governments. ANSI does not write standards; it serves as a catalyst for standards development. The Institute is a unique partnership of industry; professional, technical, trade, labor, academic and consumer organizations; and some 30 government agencies. These members of the ANSI federation actually develop standards or otherwise participate in their development, contributing their time and expertise in order to make the system work.

ANSI has accredited hundreds of standards developers to develop American National Standards across a range of industry sectors. Thousands of individuals from companies, organizations (such as labor, consumer and industrial groups), academia, and government agencies voluntarily participate and contribute their knowledge, talent and efforts to the standards development process.

ANSI determines whether standards developed by ANSI-accredited standards developers meet the necessary procedural criteria to be approved as American National Standards. The document that sets forth these criteria is entitled the *ANSI Essential Requirements: Due process requirements for American National Standards* (also known as the *ANSI Essential* Requirements). ANSI's approval of standards as American National Standards is intended to verify that the principles of openness and due process have been followed and that a consensus of all interested parties has been reached. In addition, ANSI's procedures provide for the opportunity for any interested party at any time to make a claim that an American National Standard is contrary to the public interest, contains unfair provisions or is unsuitable for national use.

The voluntary consensus standards development process has proven its effectiveness across a diverse set of industries and in federal, state and local government processes. These industries include (but certainly are not limited to) telecommunications, medical devices and systems, heavy equipment, agriculture, fire protection, information technology, petroleum, textiles, automotive, aerospace, banking and household appliances. There are now approximately 10,000 ANSI-approved American National Standards that address topics as diverse as dimensions, ratings, terminology and symbols, test methods, interoperability criteria, product specifications and performance and safety requirements. These standards development efforts continue today and are being applied to new critical areas such as the environment, healthcare and homeland security.

ANSI is the official United States member body representative in two non-treaty international standards organizations: The International Organization for Standardization (ISO) and, through the United States National Committee, the International Electrotechnical Commission (IEC). In the conformity assessment area, ANSI accredits organizations that certify that products and personnel meet recognized standards. In addition, through a joint program, ANSI and the American Society for Quality (ASQ) accredit organizations that register quality and/or environmental management systems conforming to the ISO 9000 and/or ISO 14000 series of standards.

In fulfilling its roles and responsibilities, ANSI continues to pursue its mission to "[e]nhance both the global competitiveness of U.S. business and the U.S. quality of life by promoting and facilitating voluntary consensus standards and conformity assessment systems and safeguarding their integrity." In summary, ANSI ensures the integrity of the U.S. voluntary consensus standardization system by serving as (1) an open, national forum for standards-related policy issues, (2) the recognized accreditor of standards developers, ISO Technical Advisory Groups (TAGs) and certain certification programs, and (3) a primary source of information and education on standards and conformity assessment issues.

### a.) ANSI Processes and Procedures[1]

As the only accreditor of U.S. standards developing organizations, ANSI ensures the integrity of the voluntary consensus standards development process and determines whether standards meet the necessary criteria to be approved as American National Standards. The goal of standards development within an ANSI-accredited process is to develop a document in an open and balanced process that represents a consensus of materially affected interests. Due process is critical when it comes to determining if that consensus has been fairly achieved. Accordingly, ANSI requires that a draft proposed standard be appropriately circulated (both to the consensus body and the public at large) and that an attempt is made to resolve all negative comments. If a duly constituted consensus body implements its ANSI-accredited procedures and then votes on and approves the proposed document after reviewing all unresolved negative comments and any substantive changes to the text, consensus has been achieved and due process has been satisfied. This process also requires that before any standard with objections is approved as an American National Standard an appeals process must be available and any appeals concluded. This basic formula has been the hallmark of the ANSI process for decades, and it has garnered widespread respect and acceptance.

[1] The ANSI procedural requirements for accrediting standards developers and for designating American National Standards are available on ANSI Online at <http://public.ansi.org/ansionline/Documents/Standards%20Activities/American%20National%20Standards/Procedures,%20Guides,%20and%20Forms/ER2003.doc>

If a standard is developed according to ANSI requirements, there should be sufficient evidence that the standard has a substantive reasonable basis for its existence and that it meets the needs of materially affected and interested parties. If a vote on a standard was or is somehow perceived as having been subtly manipulated, any person or entity who participated in the standards development process – whether a voting member of the consensus body or a public commenter – can appeal the decision. The grounds for an appeal to ANSI include procedural issues that relate to a lack of compliance on the standards developer's part with ANSI's Essential Requirements. Issues raised in a procedural appeal may include such concerns as a lack of balance on the consensus body, dominance by any person or entity, inadequate response to a negative comment (again whether from a voting member of the committee or a public commentator), and restraint of trade concerns. The appeals process, and the requirement that all consensus bodies seek to have representatives from a balanced group of stakeholder interests, assures that no one interest can manipulate the process unfairly. The ANSI system is designed so that contrary evidence proffered by opponents of the standard must be properly addressed and responded to or else the standard will fail to achieve ultimate approval.

In addition, proper procedures are of little value if they are not followed in practice. As a result, in addition to the review ANSI undertakes when a standard is submitted to it for approval as an "American National Standard," the Institute also has implemented a mandatory standards developer audit program. The program is designed both to verify an accredited standards developer's compliance with current ANSI requirements and to provide guidance on more efficient or effective ways to address various aspects of the standards development process.

While all American National Standards must be developed in accordance with these basic hallmarks of the ANSI process, accredited developers may satisfy these requirements in innovative ways and rely extensively on electronic communications. If there is a ready consensus by the interested parties on a proposed standard, the standard can meet the procedural requirements for, and be approved as, an American National Standard in a matter of months.

### b.) The Public-Private Partnership

While the term "public-private partnership" has been in vogue in Washington in recent years, it has been a reality for ANSI since our creation. In fact, ANSI was founded in 1918 by a group of private sector organizations and government agencies that recognized the need to have a forum in which they could address common concerns. As a private sector organization with many government members, ANSI has a strong tradition of working cooperatively with government as well as industry, organizations, and consumer interests.

ANSI is a private sector organization in which many government representatives are active at all levels, from its Board of Directors to the committees that promulgate, maintain and implement the procedures pursuant to which standards developers are accredited and American National Standards are developed and approved. Government representatives participate in ANSI delegations addressing international standardization policy issues, thereby strengthening the U.S. voice in international standardization negotiations.

When Congress enacted the National Technology Transfer and Advancement Act of 1995 (NTTAA)[2], it specifically and strongly encouraged the participation of the U.S. government, and state and local governments in the development of voluntary consensus standards. It was the clear intent of Congress that federal employees play an active role in the development of standards that will be used in regulation, procurement, and trade. This action by Congress confirmed a basic principle of the U.S. standardization system—that standards-setting is a partnership process in which government and the private sector are equal partners.

In recognition of the benefits of private standards development, the Office of Management and Budget ("OMB") has for nearly a decade directed all federal agencies to incorporate, "in whole, in part, or by reference," voluntary consensus standards for regulatory and other activities "whenever practicable and appropriate," thereby "[e]liminat[ing] the cost to the Government of developing its own standards." 63 Fed. Reg. 8545, 8554-8555 (Feb. 19, 1998) (revision of OMB Circular A-119, "Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities," October 20, 1993).

The importance of the private-public partnership was reaffirmed in a series of laws enacted by Congress in recent years, including these:

- Consumer Product Safety Improvement Act of 1990
- The National Technology Transfer and Advancement Act of 1995 (P.L. 104-113)
- Telecommunications Reform Act of 1996
- FDA Modernization Act of 1997

Each of these laws reinforced the principle that the Federal government should rely heavily upon private sector standards, and that the government should participate actively in the development of those standards and the development of policy regarding U.S. standardization objectives.

[2] Op.cit.

## 2. COMMENTS ON THE PROPOSED RULE

### Issue Identifier: BACKGROUND

ANSI strongly supports the decision made by CMS to issue foundational standards for e-prescribing and the prescription drug program. ANSI believes that the issuance of these rules and adoption of these standards will have a significant effect on the adoption and use of e-prescribing throughout the healthcare system.

Further, ANSI agrees with the background section definitions and choice of criteria for the adoption of foundation standards, and the assumptions made about standards that meet the proposed criteria.

As an editorial matter, it should be noted that some of the references to standards "accredited" by the American National Standards Institute are not correct, and should be changed for clarity. On pages 28, 39, 40, 55, 90 various references are made to standards being "American National Standards Institute accredited," "ANSI-accredited," "accredited by ANSI," and "not accredited by ANSI." In the nomenclature of standards development and approval, the organization that sponsors or hosts the development of standards may be "accredited" by ANSI if the organization's process meets *ANSI's Essential Requirements* for the development and approval of American National Standards. A standard that is developed by an ANSI-accredited standards developer and processed in accordance with ANSI's requirements may be submitted for "approval" as an American National Standard. In summary, organizations should be described as "accredited" by ANSI, standards should be described as "approved" by ANSI.

On page 39, among others, there is a reference to "ANSI-accredited standards development organization." This is a correct and accurate designation, and need not be modified.

Consistent use of this nomenclature will make the proposed language understandable and accurate. The reason for this distinction is that a standards organization may be accredited by ANSI, as required in HIPAA for its standards to be considered, while the organization may publish standards that are not processed through ANSI, and have not been approved as American National Standards.

We agree with, and endorse the criteria proposed to assess whether there is adequate industry experience with respect to proposed standards. With

respect to this issue, we believe that this is achieved by virtue of the fact that an ANSI-accredited standards developer in connection with an American National Standard must comply with the criteria established in the *ANSI Essential Requirements*. These requirements can be found on the ANSI website, at http://www.ansi.org/standards_activities/domestic_programs/overview.aspx?menuid=3

We agree with the selection of criteria for foundational standards in each of the areas addressed in the "Background" section. In particular, we wish to comment on the first criteria for assessing adequate industry experience for foundational standards, that "the standard is American National Standards Institute accredited (sic). We propose this criteria because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to address, and effectively respond to, industry needs."

ANSI believes that its process, which provides that any standard that is approved as an American National Standard must be the result of an open and transparent process, and must be produced by a consensus from a body that is balanced between users, producers, regulators and other affected interests, and is not dominated by any one interest category, is designed to assure that the resulting standard will meet the needs of materially affected and interested parties. While the consensus process does not guarantee unanimity, it does assure that all views are considered, and that contrary views are taken into account. We believe the ANSI process does provide assurance to the Department that standards selected which meet the criteria of ANSI approval will have industry recognition, will demonstrate industry acceptance and implementation, and will reflect the needs of multiple stakeholders.

In endorsing this criteria, ANSI does not mean to imply that the ANSI approval of a standard is the only way to assure industry acceptance and usage of a standard, but that ANSI approval is a useful and recognizable shorthand for determining those qualities, without further in-depth review.

ANSI is working with its accredited standards developers to arrange for the availability of all standards proposed for adoption in this rule, as well as future rulemakings related to e-prescriptions, to be available for purchase or acquisition at terms set by the publisher, and instantly downloadable from the ANSI website at: http://webstore.ansi.org/ansidocstore/default.asp

Since each standard constitutes the intellectual property of the sponsoring standards developing organization that issued the standard, ANSI cannot guarantee that all of the standards proposed for adoption will always be available through the ANSI website. However, it is our goal to maintain such availability to the extent possible. It is also our intention to develop a package of all of the standards referenced in the rule and bundle such standards for the convenience of users and healthcare providers interested in utilizing such standards.

**Submitter :** Carolyn Gingras **Date:** 04/04/2005

**Organization :** Lifespan

**Category :** Hospital

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-20-Attach-1.TXT

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

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**Submitter :** **Ms. Carla Saxton** **Date: 04/04/2005**

**Organization :** **American Society of Consultant Pharmacists**

**Category :** **Pharmacist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-21-Attach-1.TXT

CMS-0011-P-21-Attach-2.DOC

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**American Society of Consultant Pharmacists**
1321 Duke Street
Alexandria, VA 22314-3563
Phone: 703-739-1300
FAX: 703-739-1321
E-mail: info@ascp.com
www.ascp.com

April 4, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

The American Society of Consultant Pharmacists is pleased to offer comments on the proposed rule for electronic prescribing to be implemented as a part of the Medicare Part D program.

The American Society of Consultant Pharmacists (ASCP) is the international professional association that provides leadership, education, advocacy, and resources to advance the practice of senior care pharmacy. Consultant pharmacists specializing in senior care pharmacy practice are essential participants in the health care system, recognized and valued for the practice of pharmaceutical care for the senior population and people with chronic illnesses. In their role as medication experts, consultant pharmacists take responsibility for their patients' medication-related needs; ensure that their patients' medications are the most appropriate, the most effective, the safest possible, and are used correctly; and identify, resolve, and prevent medication-related problems that may interfere with the goals of therapy.

ASCP's 6,500+ members manage and improve drug therapy and improve the quality of life of geriatric patients and other individuals residing in a variety of environments, including nursing facilities, subacute care and assisted living facilities, psychiatric hospitals, hospice programs, and home and community-based care.

## I. Background

### A. Statutory Basis

#### 2. State Preemption

The proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable national scheme, physicians and pharmacists will be uncertain as to their obligations, which will impact their willingness to participate in electronic prescribing.

The interpretation proposed in the NPRM creates a system whereby the prescriber and the electronic software vendor with which the prescriber is affiliated must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug and will be extremely difficult to put into practice if applying them requires information at the point of prescribing, which is not available in the current system.

Creating a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a wide variety of federal and state laws affecting electronic prescriptions.

In the long-term care setting, the numerous changes in residents' level of care illustrates the need for the e-prescribing model to be available for prescriptions covered by all payment types - not just Medicare Part D. For example, a nursing facility resident who has Part D benefits might be hospitalized, return to the facility under Medicare Part A, and revert to Part D after their Medicare Part A benefits conclude. Without consistent, overarching e-prescribing standards, using electronic prescribing while maneuvering through the frequent pay status changes would be overwhelmingly burdensome to the pharmacy, facility staff and prescribers.

In addition, for e-prescribing to work in the long-term care setting, the state and federal survey processes must accept electronic records and electronic signatures. Since state survey agencies within the Department of Health usually conduct both state and CMS surveys, these agencies and their surveyors will need to become educated in accessing electronic prescription information. Regulations and guidelines might also need to be revised to accommodate current and emerging electronic processes.

These proposed rules also do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different state-specific regulations pertaining to the record keeping of controlled substance prescriptions and these state-specific regulations are even more unique for long-term care pharmacies and facilities.

## D. Current Prescribing Environment

The current prescribing process environment outlined in the proposed rule focuses primarily on the ambulatory setting (e.g., community-dwelling beneficiaries, retail pharmacies and prescribers' offices). The Part D program is indeed an outpatient benefit, but residents residing in skilled nursing facilities and assisted living facilities are considered "outpatients," despite the location of their residence. Many of these residents, actually the majority, will qualify and receive Medicare Part D benefits. Residents in long-term care facilities are among the frailest elderly largely because of their numerous comorbidities. In 2000, a national survey of nursing facilities found that the average nursing facility resident took 8.1 routine medications, and 41.1% took nine or more routine medications. [1]

These long-term care settings have a different prescribing process involving more entities than the typical two parties (pharmacy and prescriber) seen in the ambulatory environment. In fact, there are at least three parties involved in the medication use process in nursing facilities and assisted living facilities:

- Nursing facility staff
- Dispensing pharmacy (or pharmacies)
- Prescriber

Currently in these long-term care settings, the prescribing process can be summarized in the following steps:

1. The facility nurse usually performs the initial assessment of the resident upon onset of a new symptom(s), unless the prescriber happens to be visiting the facility at that time. According to the nursing facility regulations found in the State Operations Manual at Tag F-387, *"A physician must see the resident at least once every 30 days for the first 90 days after admission and at least once every 60 days thereafter."*
2. The nurse contacts the prescriber, whose office is offsite, for appropriate treatment options and subsequent orders. Whether the nurse or prescriber initiates assessment, the prescriber ultimately utilizes resident-specific information from the medical chart, which is housed at the facility – not the prescriber's office. Reviewed information includes current medications, medication history, demographics (e.g., weight, height, age), drug allergies and concurrent diagnoses and/or symptoms.

[1] Tobias DE, Sey M. General and psychotherapeutic medication use in 328 facilities: a year 2000 national survey. *Consult Pharm* 2001;16:54.

3. Orders (prescriptions) are usually received in a verbal or faxed format.
4. The nurse enters this order into the resident's medical chart.
5. The nurse then faxes or phones in the prescriber's order to the dispensing pharmacy chosen by that facility/resident.
6. The dispensing pharmacist conducts a prospective medication review by examining potential drug allergy conflicts, drug-drug and other interactions, and other potential medication-related problems. The pharmacy fills the prescription using the NCPDP Telecommunication 5.1 Standard for claim submission. Messages received pertaining to third party coverage, such as formulary information or prior authorization, are considered by the pharmacy and communicated to the facility and prescriber by phone or fax for resolution. Documentation necessary to fulfill these coverage requirements is usually provided by the facility staff, since they have primary access to the resident's medical chart. Although, prescribers and pharmacy staff are also involved in the process.
7. The dispensing pharmacy delivers the medication to the facility where the nurse accepts and notates receipt of the medication. Nursing facilities are required by federal regulation to provide prescribed medications to residents in a "timely manner." Regulations located at Tag F-425 of the State Operations Manual from the Centers for Medicare and Medicaid Services states, "*A drug, whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort or endangers his or her health and safety, then this requirement is not met."*
8. Prescription renewal is documented by the physician when he/she signs each resident's current orders during the recapitulation process, usually occurring every 30 days. For medications warranting refills, this need is either communicated to the pharmacy by the facility or it is automatically refilled by the pharmacy based on the days supply of the dispensed medication.

## E. Current E-Prescribing Environment

The current e-prescribing environment is virtually non-existent in the long-term care industry due to many of the same barriers outlined in the NPRM, including the costs of buying and installing a system, training involved, time and workflow impact, lack of reimbursement for costs and resources, and lack of knowledge about the benefits. However, the distinct difference in the long-term care setting is that all of these potential barriers apply not only to prescribers and pharmacies, but also the nursing facilities. To reiterate the current prescribing environment in long-term care, there are at least three parties involved rather than the two parties currently involved in the ambulatory setting,

While pharmacies rely heavily on computer technology and some are already capable of utilizing e-prescribing due to their use of NCPDP communication standards, many nursing facilities have yet to adopt technology on a large scale other than the one or two computers in their administrative and billing offices. Computer access at nurses' stations is quite limited. In fact, most long-term care facilities still utilize manual charting processes. Therefore, introducing e-prescribing into the long-term care setting will be a challenge. Nonetheless, the closed system created by the nursing facility and limited number of prescribers and pharmacies provides an atmosphere that would enable long-term care to be a leader in e-prescribing if the stated barriers are overcome.

NCPDP, at the request of industry participants, has created a new work group to address these special needs of the long-term care industry. NCPDP Work Group 14 for Long Term Care, in conjunction with the other NCPDP Work Groups, will:

- Guide and advise payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation,
- Support data processing initiatives, and
- Provide design alternatives for standards used within the long-term care industry.

It is expected that long-term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy. Some of these unique needs include the following:

1. The billing offices of the pharmacy and nursing facility communicate residents' billing status to one another, which can change according to the level of care deemed necessary by a resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow coordination of benefits (COB). As outlined previously, there is an increased need for process adaptations and communication between health care professionals in long-term care to assure nursing facilities meet the required federal regulation to provide prescribed medications to nursing home residents in a "timely manner".
2. In the long-term care setting, prescribers and facility nurses often do not know a resident's pharmacy benefit eligibility and coverage, making prior authorization and formulary processes more difficult and time-consuming. The industry has relied on the long-term care pharmacy provider to obtain and provide this information. If this information were made available to prescribers and facility staff at the time of prescribing, much time would be saved by all parties.

3. Medical records for nursing facility residents are located at the nursing facility, not in the physician's office. This causes difficulty when resident information housed in the medical chart is needed by the prescriber or pharmacy. Currently, the information gathering process is often left up to the facility staff.

For these reasons, an electronic health record (EHR) is ultimately needed for e-prescribing to work most efficiently in the long-term care setting.

## F. Evolution and Implementation of an Electronic Prescription Drug Program

As a participant of the National Council for Prescription Drug Programs (NCPDP), ASCP appreciates CMS acknowledging NCPDP SCRIPT Standard Version 5.0 as a minimum standard for electronic prescribing programs. It is important to reiterate that this standard is a minimum or a "floor" from which to grow in the future. By naming this standard as the minimum, industry is provided a "floor" that it can support in a timely manner. We feel that this will ensure adoption of electronic prescribing without stifling industry movement to future versions, as business needs arise.

ASCP is in agreement with an NCPDP proposal whereby newer versions are adopted and older versions are retired to allow maximum flexibility for the industry as it upgrades systems. It is important not to negatively impact the long-term care setting by naming an e-prescribing version that the industry is not able to support.

It is expected that long-term care participants of the NCPDP Work Group 14 will be bringing recommendations specific to long-term care to NCPDP for the development of future electronic prescribing standards.

## G. Electronic Prescription Drug Program

- **Formulary and Medication History Standards**

As stated above, currently the billing offices of the pharmacy and nursing facility communicate billing status to one another, which can change according to the level of care deemed necessary by the resident's medical condition. Because these billing changes can directly impact the resident's prescription benefit, including eligibility and co-insurance, real-time eligibility information must be communicated electronically from the facility to the pharmacy, prescriber, and the PDP to facilitate the formulary and prior authorization processes. Including this specification in the e-prescribing process will allow COB and the timely delivery of medications to facility residents. To our knowledge, no current formulary and benefit data standards accommodate these specific needs.

- **Drug Information**

Research suggests that significant inconsistencies exist in the creation of drug information databases utilized in health care software. In addition, the assignment of clinical significance to drug interactions and other drug information is critical to the acceptance and accurate utilization of such facts by health professionals.

In response to the overwhelming number of complaints and errors associated with the multitude of drug information messages in software programs, the United States Pharmacopeia Therapeutic Decisions Making (DTM) Expert Committee formulated a methodology to establish a hierarchy of evidence that defines drug-drug interactions and decides what types of evidence to consider with regard to such interactions. USP and other pharmacy associations have been working with a contracted research team to apply and assess this evidence methodology. In addition, the USP Convention recently passed a resolution pertaining to this issue:

"*Evidence-Based Methodologies and Algorithms for Decision Support Used in E-Prescribing and Pharmacy Computer Systems" – USP resolves to work with appropriate stakeholders to continue developing evidence-based methodologies and algorithms for decision support in areas such as drug-drug interactions, and to expand efforts to other alerts and recommendations for use in e-prescribing technologies and pharmacy computer systems. Furthermore, USP resolves to explore the feasibility and advisability of extending this approach to other information domains in the interest of the public health and patient care."*

For these reasons, we recommend that any drug information standards developed as a part of the Medicare Part D electronic prescribing program include mandates for evaluating the evidence base, clinical significance, and accuracy of such information. As learned from past experience, an overload of information to providers does not always result in the provision of efficient and effective health care.

## H. Summary of Status of Standards for an Electronic Prescription Drug Program

For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. Including long-term care providers in these pilot projects will help to

identify and define the industry's unique needs and work to promote adoption of electronic prescribing in this setting.

## II. Provisions of the Proposed Regulation

### B. Proposed Definitions

As mentioned previously, effective electronic prescribing in the long-term care setting must include communication with the nursing facilities where beneficiaries reside. For this reason, we recommend amending the definition of "E-prescribing" to state:

> E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, *nursing facility*, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.

E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information. This definition involves electronic transmission through mechanisms such as the Internet, Extranet, leased lines, dialup lines, private networks, and physical movement of data from one location to another. However, messages that leave or enter a system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions. Therefore, we recommend inclusion of a definition for "Non-EDI Messages" to read as follows:

> Non-EDI message means a message that leaves or enters a system (including long-term care facilities and/or pharmacies) as an image, either via fax or email, that are not included in the electronic prescribing standards. This does NOT include handwritten prescriptions that are faxed, but does include legal, electronic prescriptions/orders that are formatted to be electronically received by a fax machine. Due to the nature of such an electronic prescription/order, the prescriber's express authorization and credentials have already been validated and documented prior to transmittal.

## IV. Regulatory Impact Analysis

### A. Overall Impact

In the March 9, 2005 issue of the *Journal of the American Medical Association*, three articles explored the challenges and benefits of computerized physician order entry (CPOE) systems and clinical decision support systems. It can be easily assumed that these study results will compare with the potential

challenges and benefits resulting from electronic prescribing as envisioned by the Medicare Modernization Act. Researchers found, when widely implemented, a CPOE system "facilitated 22 types of medication error risks." Examples of these errors included:

- Fragmented CPOE displays that prevent a coherent view of patients' medications
- Pharmacy inventory displays mistaken for dosage guidelines
- Ignored antibiotic renewal notices placed on paper charts rather than in the CPOE system
- Separation of functions that facilitate double dosing and incompatible orders
- Inflexible ordering formats generating wrong orders

Researchers found that 75% of staff reported observing each of these error risks, indicating that they occur weekly or more often.

Based on this evidence-based information, it is reasonable to assume that electronic prescribing will cause or potentate new errors while reducing "traditional" medication errors (e.g., those resulting from poor handwriting). These new types of errors will need to be expected and proactively prevented, to the extent possible. It is important to ensure those participating in electronic prescribing programs are aware of the patient safety benefits of such technology while remembering to watch out for new errors that might come forth.

### B. Impact on Health Plans/PBMs

The NPRM proposes that "health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance." To reduce potential confusion, it is important to differentiate health plans from PDPs. Consequences of medication-related problems (e.g., adverse events) resulting in physicians' visits, emergency room visits, and hospitalizations are not paid for by the PDP, but are instead paid for by the patient's medical insurance or general health plan. To maximize profits, PDPs will be motivated to decrease both the costs (per prescription) and usage (number of prescriptions) of medications. Based on this theory, PDPs will not be motivated to improve patients' compliance with their medication regimens. In fact, the opposite (non-compliance) is financially beneficial to the PDP. Therefore, to minimize misinterpretation, additional language is recommended to clarify the use of the term "health plan."

### C. Impact on Prescribers

If e-prescribing in the long-term care setting is inconsistent with e-prescribing processes in the community, this could add an unnecessary strain to a

prescribers' practices if they serve both ambulatory and nursing home patients. Prescribers who adopt e-prescribing in their community practice may choose not to work in the long-term care setting unless a similar process is utilized in the nursing facility. It is already difficult for some rural nursing facilities to attract or keep prescribers who are willing to provide services to their residents due to time constraints, liability issues, regulatory requirements, and lack of reimbursement. Compounding these existing issues with e-prescribing inconsistencies could potentially impact the willingness of prescribers to practice in the long-term care setting.

### F. Impact on others

The overall impact of electronic prescribing on long-term care nursing facilities and the pharmacies and prescribers serving those nursing facilities is not addressed in the NPRM.

- In the long-term care setting, there is a need to develop technology for a three-way communication between off-site prescribers, long-term care provider pharmacies, and nursing facilities.
- The long-term care setting requires a more complex process utilizing a three-way communication for an e-prescribing model to be successful. For this reason, PDPs, long-term care pharmacies, prescribers, and nursing facilities may incur additional costs beyond those incurred in the ambulatory setting.
- In the nursing facility, there needs to be incentives for the training of nursing staff, which frequently turn over, and the purchase of computers. Most nursing facilities currently have very few computer workstations and still use a manual charting process.
- As discussed previously in the "Impact on Prescribers" section, prescribers who serve both ambulatory and nursing facility patients might be unduly strained if the long-term care setting is excluded from a standardized e-prescribing process.

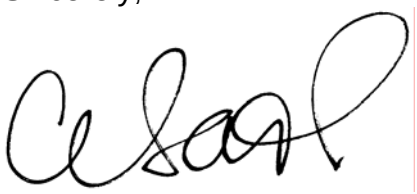
### I. Conclusion and Alternatives Considered

In this document, we have identified reasons why the long-term care setting differs from the ambulatory or community setting. For electronic prescribing to work in the LTC setting, technology needs to be developed for a three-way communication between off-site physicians, nursing facilities, and long-term care provider pharmacies. Standards for these communications have yet to be developed and utilized. Since pilot testing is proposed in the NPRM to identify and test standards without adequate industry experience, ASCP requests that future pilot testing include the long-term care industry. We request that CMS prioritize the need for information pertaining to the long-term care industry information as it pertains to electronic prescribing and consider pilot project

proposals from long-term care providers. This will enable identification and definition of the unique needs in this setting. ASCP would be pleased to offer assistance throughout the pilot phase and to provide additional information, as needed, regarding the impact of electronic prescribing in the long-term care setting.

Thank you for your consideration of our comments and suggestions. If you have questions or concerns, you may contact Carla Saxton, Professional Affairs Manager, at the following email address: csaxton@ascp.com, or phone number: (703) 739-1316 ext. 129.

Sincerely,



Carla Saxton, RPh, CGP
Professional Affairs Manager
American Society of Consultant Pharmacists

**Submitter :** **Dr. Janet Root** **Date: 04/04/2005**

**Organization :** **Utah Health Information Network**

**Category :** **Other**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Pages 1 - 9 of Attachment

Regulatory Impact Analysis

See pages 18 - 36 of Attachment

Collection of Information Requirements

See page 17 of Attachment

Provisions of the Proposed Regulation

See pages 10 - 16 of Attachment

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*Utah Health Information Network* • 151 East 5600 South, Suite 320 • Murray, Utah 84107 • Phone 801-466-7705, Fax 801-466-7169 • www.uhin.com

April 4, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human
Services, Attention: CMS–0011–P, PO
Box 8014,
Baltimore, MD 21244–8014

Dr McCellan,

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act. As a state-wide network engaged in exchanging administrative information for over 10 years, the UHIN Community was deeply involved in the implementation of the HIPAA transactions and we believe there is a lot to be gleaned from that experience.

**Standards** The first HIPAA lesson is the need for true unambiguous standards. While the NCPCP Script is an admirable standard its implementation will be subject to variation if HHS only adopts the *Standard* HHS should adopt a specific implementation guide of the NCPDP Script. Otherwise, it is likely that grave differences in implementation will arise and interoperability will become a significant barrier to adoption.

**Financial impact.** Second, the UHIN Community believes that implementation of these messages will have a significant *financial impact* upon physicians and pharmacists, especially small physician and pharmacy businesses. HIPAA resulted in vendors charging significantly for both HIPAA upgrades and for the ability to exchange messages. Several large practice management vendors required their customers to utilize certain exchange entities thereby reducing competition in that market. In all likelihood, this will happen again. In all likelihood this will happen again. Thus much of the potential economic incentive to adopt the MMA messages will be eroded, particularly for smaller entities. It is vital that rural hospitals, pharmacies and providers be protected by this economic impact. Utah is largely a rural and frontier state; we cannot afford to lose these critical access entities.

**DEA**. Utah is poised to adopt electronic prescribing. One major barrier is the lack of action on the part of the DEA to designate a legal electronic signature mechanism. The UHIN Community urges HHS to encourage prompt action on the part of the DEA in resolving this issue.

**Privacy** The UHIN Community has expressed some doubts about privacy issues that the proposed exchanges may engender, particularly in the exchange of medication history and medical history. We understand that payers largely have the right to know both the medication and medical history of their members. However, that right does not extend to pharmacists and physicians. The proposed exchange of medical history from any pharmacy and physician to any other would create the need for these entities to know exactly what patient information could be exchanged and what could not. In addition, such an exchange would necessitate the ability to *respond* to an electronic query. This could impose an additional IT burden on pharmacists and physicians.

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act. We believe this act to be a significant step in moving the entire health care community towards exchanging clinical information which will contribute not only to improving patient care and safety, but also potentially reduce health care costs.

Sincerely,

Bart "C" Killian
Executive Director

# Utah Health Information Network

Response to the Medicare Modernization Act Proposed Rules

## I. Background

Comment about:

*Prescribers may not have access to the latest drug knowledge, do not have a completely accurate medication list or do not have a medical history for their patient, and, may be unaware of potential drug-drug or drug-disease interactions or duplicate therapies.*

*Pharmacists often have difficulty reading handwritten prescriptions and have little or no information about the patient's condition for which the prescription is written. May have to contact the prescriber by phone to clarify what is ordered*

*Mak[ing] changes in the prescription results in delays for the patient and time consuming for the prescriber and the pharmacist.*

*Little or no feedback is given to the prescriber on whether a prescription was filled or refilled*

**Comment:**

There was agreement that the current prescribing process is prone to errors. Prescribers do not have easy access to formularies and preferred drug lists; providers do not have easy access to unbiased drug information. Usually both formularies and drug information are printed (and are thus mostly unused). Even when a provider downloads them into software like Epocraties, it often takes too much time to use them on an extensive basis. Hence use of formularies is usually restricted to the provider's top 2 -3 payers and familiarity with drugs is limited to very common drugs.

UHIN providers raised both pro and con points regarding feedback to the provider on whether or not a prescription was filled or refilled. While there was agreement that this information may improve quality of care, some physicians are concerned about additional liability and additional uncompensated work. However, **physicians are in agreement that they do not want to know whether or not a prescription was filled on every prescription they write**. If this information becomes available, they only want to know it about certain prescriptions. It is not efficient for them to have this information about every prescription.

Pharmacists usually do not have a complete list of drugs the person is taking. Usually their only list of drugs a person is taking comes from their own internal data bases. Info on drug-drug interactions from the PBM is spotty at best. Therefore most of the drug-drug intervention is primarily driven off the *pharmacists* data base, not the PBMs. Will the adoption of these messages assist pharmacists in preventing drug-drug interactions? One important point is that there needs to be a system to rate the potential magnitude of a drug-drug interaction; is it minor, moderate or life-threatening?

There seems to be an assumption that the prescriber will have done any medication history checking prior to the patient presenting at the pharmacy. How will the pharmacist know that this has been done? No EDI process is ever 100%; pharmacists need an indicator that medication history has been checked (or not) on incoming prescriptions.

Comment about:

- *"(i) Information on the*
  - *drug being prescribed or dispensed and*
  - *other drugs listed on the medication history, including information on*
    - *drug-drug interactions,*
    - *warnings or*
    - *cautions, and,*
    - *when indicated, dosage adjustments*

**Comment:**

1 Concern was raised about the source of the information on the drug being dispensed

- Would this source of information be neutral or would it be advertising information from the manufacturer?
- Will the drug information data base include negative clinical trials information? Will it include information from the FDA?
- Which data base will be used to monitor potential drug-drug interactions, warnings, and cautions?
- How often will the data base be updated?
- Will all Medicare Part D contractors use the same data base?

The general sense was the different data bases give different information and are more or less reliable

2 Other issues

- Will the PBM be charged with keeping dosage adjustment information? How will they receive this? What about the physicians sample closet –will those types of dosage adjustments be tracked? If yes, how?
- Which message would be used to convey drug-drug interactions, warnings, and cautions?
- Which NCPDP message would be used for drug dosage adjustment information?

Comment about:

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and POC vendors.*

*The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*

**Comment:**
Attention was focused on the last bullet which describes an information exchange of medication history between *payers*, *prescribers* and *dispensers* as if all three entities could potentially be data sources. This particular recommendation does not follow the NCVHS recommendation which limited this exchange to prescribers querying PBMs

There was agreement that an expectation that all three parties might be data sources would dramatically increase the complexity and cost of implementation, particularly for dispensers and prescribers.

There was also concern about managing privacy issues if all three entities became data sources. While it is true that if a person holds insurance, there is usually a clause in their contract which states something to the effect that they are allowing the insurer access to their medical information, usually patients who see a need will actively segregate their information so that certain portions of the health care industry do not know all their medical information. However, what if a patient does not want their PCP to know that they had a test for STDs because the PCP is a personal friend of their spouse? While the contract with the payer may require the patient share all medical information with the payer, does it require that the patient share all medical information with ALL their health care providers? There was great concern about the privacy issues such an exchange might open up. While the goal of higher quality care is commendable, should it trump an individuals' right to privacy in all cases?

There was a question about whether large institutions would need to segregate information about inpatient vs ambulatory care. This could be difficult for them to accomplish

Comment about:

*Statute: an electronic prescription drug program includes the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed.*

*"Medication history" refers to drugs that have been prescribed to the individual*

*"Medical history" relates more broadly to information about the patient's health care and health status (for example, allergies, laboratory test results, and chronic conditions)*

*Intend to propose standards for communicating medical history at a future date.*

**Comment:**

Concern was expressed about how plans were going to accomplish the statute, namely to transmit medical history related to a Part D drug. This will be difficult to impossible because

- Patients often seen providers for more than one reason (particularly patients in this age group)
- Providers often prescribe drugs for off-label use
- Hence there is no link between the prescription and the diagnosis or problem list.

There was concern expressed about who was going to do Medication Therapy Management? The physician? The PBM? Who?

Comment about:

*"(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed*

**Comment:**

Concerns were raised about who determines what therapeutically appropriate alternatives are

- The group estimated that many drugs are not used for FDA approved diagnoses (off-label use) How will a payer determine what is a therapeutically appropriate alternative if they do not know what symptoms (presumptive diagnosis?) the drug is being prescribed for?
- Given the relatively common off-label use of drugs, how will a payer, whose primary sources of information on a patient are claims, link prescriptions with claim data?
- Given the relatively common off-label use of drugs, how is a plan to link the use of a Plan D drug with a specific portion of a person's medical history? If a drug is being used for off-label purposes how will a 'therapeutically appropriate alternative" be determined?
- What diagnoses code list would be used? Physicians don't use ICD-9 diagnoses for presumptive diagnoses or for true clinical diagnoses
- Who will make the decision about what is 'therapeutically appropriate"?

Pharmacists would like to get information on which brand of a drug is *cheaper for the particular plan*. They may get indications regarding whether it is permissible to substitute a generic but they still don't know WHICH generic to use; they are not told of any pricing arrangements between plans and pharmacy manufacturers

Comment about:

*"(B) APPLICATION TO MEDICAL HISTORY INFORMATION.--Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal ... of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved*

**Comment:**
What is meant by the term *medical history*? What does this encompass? For example, the medical history of a person with asthma might need to involve such factors as triggers, number of recent exacerbations (or a history of exacerbations), etc. Who will make a determination of what constitutes portions of a medical history that are associated with a specific drug?

There was concern about how a PDP could accurately link medical history (presumably derived from claims). Will the PDP be requiring physicians to respond to inquiries about medical history in order to participate with the plan? Responding to an inquiry about a person's medical history could create an enormous burden upon small to moderate sized physician practices Will there be any compensation for this type of work?

What kinds of standards will be used to make the determination that x portion of a person's medical history is linked with a particular Plan D drug? What about medical history being requested from a physician who did not that another physician had prescribed a certain drug? How is the physician going to know what information to respond with?

Pharmacists pointed out that the data on the prescribing physician that they receive is often inaccurate. This will further challenge the ability of the PDP to link medical data with prescription data when the prescribing physician data is not accurate

**The group strongly recommends *lengthy testing* prior to adoption of any medical history message as well as an *evaluation of the processes* by which the various parties (PDPs, pharmacies, and physicians) might respond to requests for medication history.** Because the rule discussion does not mandate the participation of physicians or dispensers there needs to be extensive testing of the implementation of whatever message is chosen and its impact on the ability of physicians and dispensers to respond. However, one criterion for adoption is that the messages not place an undue burden upon the respondent Medical history could pose an enormous burden to implement

Comment about:

*"(D) TIMING --To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis*

**Comment:**

There was concern about the phrase "to the extent feasible". If the messages are not done real time, these messages will not be adopted by physicians or pharmacists Real time should be defined as less than a 3 second response

One member of the group has been involved at NCPDP for some time. He mentioned that the Formulary and Benefits message is intended to be a batch download to a formulary repository organization. The UHIN group still wants the query to the formulary repository should be less that 3 seconds. However, the actual message being proposed (the NCPDP Formulary download) would not be a 'real time' message Only the query to the formulary repository would be real time

Physicians often state that they don't want to support the formularies of dozens (sometimes hundreds) of payers. If formulary repository organizations are going to evolve, their use has to be geared towards creating a favorable climate for physicians to use them. For-profit, charge-by-the-query models may face an uphill battle in adoption.

Comment about:

*These proposed foundation standards are a first step toward a more complete set of standards required for an electronic prescription drug program under the MMA*

*Additional final standards will be identified, pilot tested, and proposed through separate processes in accordance with the time frames set forth in the statute and will build on these foundation standards*

*NCVHS recommends that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future*

**Comment:**
Commenters were in agreement that EMRs need to focus on a single standard

There were no comments on State Preemption or on Anti-Kickback or Stark provisions

Comment about:

*HHS believes that it is necessary to have a unique identifier for these transactions*

*The NPI* is the preferred option, because it is a standard that many entities will be required to use under HIPAA*

**Comment:**
UHIN agrees with HHS that these transactions need a unique identifier for prescriber and dispenser. UHIN suggests that HHS stress that EMRs must be able to handle NPI or other types of national identifiers

**UHIN recommends that HHS implement the NPI in synch with the HIPAA schedule.** The NPI must first be proven to be a workable, low-error system before it should be adopted by clinical systems

Comment about:

*ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors*
*Meets Adoption Criteria:*
*ASC X12N 270/271 are ANSI-accredited standards*
*the standards are adopted HIPAA standards*
*the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

**Comment:**
There was concern about the phrase:

*. . .level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request*

The primary problem with the current HIPAA 270/271 transaction implementation is that payers are allowed respond with a simple 'yes this person is a member' or 'no this person is not a member' and to not provide any additional information. Payers are also allowed to set up individual web sites using DDE which can have no relation to the 270/271. As a result 271responses to the 270 are often too meager to be of use to providers Or, to obtain a more robust response, the provider has to visit many individual payer web sites which is time consuming and not productive. This has created a state where there is little impetus for providers to use the 270/271 UHIN suggests that the PDPs be required under the MMA to respond with two pieces of information (1) this person is or is not a member of the PDP, and (2) if the inquiry includes the proposed prescription (in NDC), the response include whether or not this particular drug is covered under this persons PDP benefit Also, UHIN suggests that PDPs not be allowed to use DDE for this transaction It is not efficient for physicians to have to visit many web sites to obtain eligibility information. The potential offered in HIPAA for this transaction has not been realized *for providers* because of these two issues

Comment about:

*Formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub*

*RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be considered for adoption as an ANSI-accredited standard*

*We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards*

**Comment:**
The UHIN group was not in favor of including the *Formulary and Benefits*, and *Medication History* Standards as foundation standards for either pharmacists or physicians No one feels that there is sufficient industry experience to justify this approach

Pharmacists do occasionally receive formulary and benefits information but have not had enough experience to recommend forgoing a pilot None of the physicians in the review had ever had this type of information in an electronic form

There was a question about whether reversed/voided prescriptions (prescriptions that were written but not picked up by the patient) would be included in the Medication history Physicians suggested that there could be value in knowing that information

There was concern that, if the RxHub protocols are only now being adopted by NCPDP, how much experience with these messages *in a rigidly standardized form* has the industry truly experienced? Typically when a message has yet to be adopted by an SDO, the implementers of that message tweak it to meet their individual needs. Even when a message has been adopted, there is usually a spread of implementation that more or less conforms to the standard UHIN has no evidence that *Formulary* and *Medication History* Standards have truly been tested in a standardized and widespread fashion

Although UHIN is aware that RxHub and others have used these messages, *we do not believe there is wide-spread industry experience yet*

Comment about:

*The standards cover a range of formulary and benefit data, including information on the--formulary (for example, therapeutic classes and subclasses); formulary status (for example, drugs that the benefit plan considers to be "on formulary"); preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another)*

**Comment:**

There were concerns about plans suggesting an alternative therapeutically appropriate drug for off-label use of prescriptions. People questioned whether a plan is in a position to suggest therapeutically appropriate formulary alternatives if they do not know the diagnosis (or the presumptive diagnosis). There is a problem with using ICD-9 or CPT codes for diagnoses in this situation. ICD-9 and CPT have largely been developed to bill, not to record detailed diagnoses or presumptive diagnoses. However, there is the issue that physicians and hospitals will mostly like be resistant to having to deal with yet another code list (like SNOMED). The group questioned how the PBM might obtain that information. For example, if the diagnosis is pneumonia, the PBM would need to know that it is pneumoccocal pneumonia vs. mycoplasmic pneumonia in order to be able to recommend a therapeutic alternative.

There is also the case when a prescription is being used as a therapeutic trial (there is only a presumptive diagnosis). Health care claims only code for diagnoses; they do not indicate if the diagnosis is tentative or firm. How would those situations be handled?

There was a question about where information on a drug would originate. Would this information come from the manufacturer? Would additional clinical trial information be included? Would it include FDA information? There is concern about the need for unbiased drug information, with the caveat that people know that the pharmaceutical manufactures fund most of the research on drugs and that, therefore, historically, much of the information on drugs has not come from an unbiased source.

Comment about:

*NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry.*

*Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs.*

*Third, the NCPDP SCRIPT Standard transactions we propose for adoption are recognized as the industry standard.*

**Comment:**
One of the criteria for by-passing the pilot is:

*The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner.*

Based on UHIN's experience in implementing HIPAA, UHIN recommends that HHS go further than simply adopting NCPDP Standards; **HHS should adopt specific implementations of the NCPSP Script Standard.** We recently did a detailed review of the SureScripts implementation of the NCPDP Script Standard and while what SureScripts is implementing is in compliance with the Standard, they have created their own interpretation of that Standard. For example, they often do not send elements or segments that are not required in the Standard.

This is going to create a hodge-podge of implementations of the NCPDP Standard. UHIN recommends the HHS adopt specific implementation guides of the NCPDP Standard rather than just the Standard. As we have learned from HIPAA, 'standards' which are relatively permissive get implemented in a huge variety of ways creating deep interoperability issues.

UHIN's other comment about NCPDP Script is that it appears to be designed for a mail boxing type of approach to exchanging information. Will a mail boxing approach meet the real-time requirement specified in the statute? A truly interactive system requires pushing information instantaneously between trading partners. We believe use of the GETMES will encourage many less than real-time implementations.

There is a feeling that while the parts of the NCPDP Scripts messaging standard which are being proposed for adoption as foundation standards have been tested, they have not been equally tested by all three components of the messages in the MMA rule, namely the providers, the pharmacies, and the PBMs.

It is our understanding that the parts of NCPDP Script which are being proposed as foundation standards include *New Rx, Refills, Changes, Cancellations, Formulary and Benefits,* and *Medication History.* UHIN does not feel that the *Formulary and Benefits*, and *Medication History* portions of the NCPDP Script message have been adequately implemented by all the entities who would utilize the final standard. Neither pharmacists nor physicians think that they have adequate experience with these messages to say that they know they will work. They do not think it has been applied in multiple e-prescribing programs with more than one external health care partner to an adequate degree. To our knowledge, SureScripts is the only program which has implemented even the *New Rx, Refills, Changes, Cancellations* messaging standards across many entities and it is our impression, talking from physicians and pharmacists who have participated in the SureScripts implementations that it could be argued that further work needs to be done on these standards prior to adopting them on a widespread basis.

E-Prescribing standards need to be adopted not only message-by-message but also implementer by implementer. One of the biggest mistakes of HIPAA was to mandate that everyone do all the transactions all at once. This approach created a highly chaotic implementation environment mostly to the detriment of the providers. We strongly recommend that HHS adopt a more

measured approach not only to determining the order in which these messages are implemented, but also the entities which would implement them.

There was concern raised about whether the PBMs were going to have more voice about treatment for patients The thrust of the MMA act appears to reduce costs by having input into the prescription at the point of writing the prescription. Concern was expressed that this would interfere with quality care tailored to the needs of the individual patient

It was pointed out that pharmacy and prescribers are somewhat at the mercy of their vendors in terms of what they can implement and how fast they can bring it up. It was also pointed out that pharmacists and providers would bear the brunt of the cost of bringing up these systems and yet much of the benefit would be conferred to the PDPs. There were questions about the motivation for providers and pharmacies to participate in these exchanges There is no obvious motivation written into the rule as it currently stands.

UHIN recommends that the messages in with a solid outline (——) in Figure 1 be adopted as foundation standards UHIN recommends that the messages in outlined with a broken line (– – –) in Figure1 be subject to further testing prior to adoption In particular, UHIN recommends that both the Formularies and Benefits and the Medication History message be tested in the arena of making that information available to pharmacists (upon request) Although the model is that the physician makes these inquires prior to the patient presenting to the pharmacy, there is no guarantee that the physician has actually done so; there is no way for the pharmacy to know this activity has occurred.

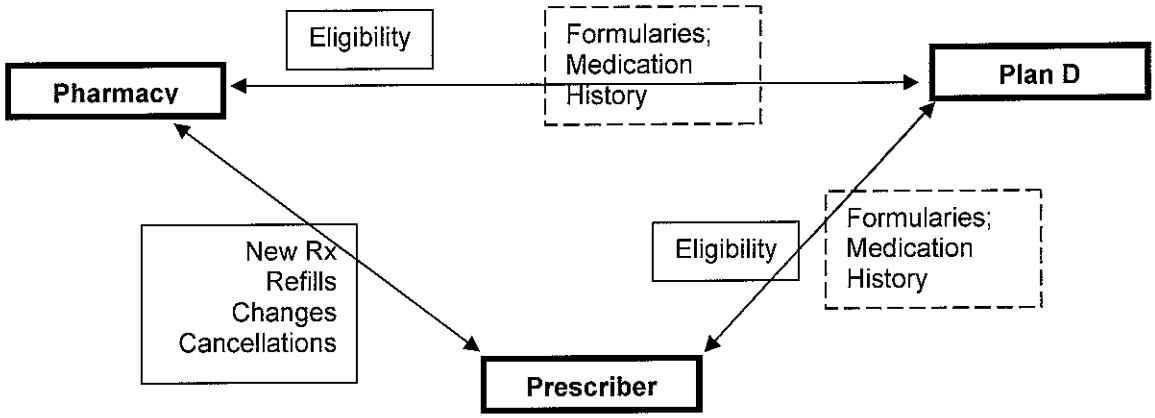


Figure 1. UHIN's recommendations for foundation standards

Comment about:

*Except not these parts of NCPDP Script:*

*the Prescription Fill Status Notification Transaction (and its three business cases*

*Prescription Fill Status Notification Transaction - Filled,*

*Prescription Fill Status Notification Transaction - Not Filled;*

*Prescription Fill Status Notification Transaction – Partial Fill)*

*These transactions will not be adopted at this time because, there is not adequate industry experience*

**Comment:**

UHIN suggests that the exchange of the Prescription Fill Status Notification Transaction be reviewed for both patient privacy and physician liability issues as well as message functionality prior to adoption Physicians are cautious about any information that might increase their liability burden. If a physician knows that a patient has not picked up a particular medication, what kind of liability does this impose? There is an impression that the liability burden varies from state to state.

Comment about:

*NCVHS Testimony.*

*most health plans/PBMs currently have e- prescribing capability either directly or by contracting with another entity. Therefore, conducting an electronic prescription drug program would not be an additional burden for those plans. Since these standards are already in use, we believe the requirement to adopt these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).*

**Comment:**

There was agreement that the Plan Burden was estimated correctly

Comment about:

- *2003 - 3.1 billion retail prescriptions*
- *Estimate: 2006 as about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan*
- *Estimate 5 and 18 percent of prescribers are conducting e-prescribing*
- *some studies have indicated increased prescriber interest*
- *Predict that MMA will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used.*
- *Predict: the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years*
- *The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of—*
- *Publicity surrounding the Medicare Prescription Drug Program;*
- *More publicity about the benefits of e-prescribing and the experience of prescribers who are participating,*
- *Increased emphasis on health information technology in general,*
- *Potential cost savings to providers using e-prescribing; and*
- *The availability of incentives for participation.*

**Comment:**
There was agreement that the anticipated 10% annual increase may be overly aggressive Also, if 5 to 18 percent of prescribers are conducting e-prescribing that mean that 95 to 82% are not UHIN feels this is a significant portion of the industry that has not had experience with e-prescribing UHIN recommends a measured approach to implementing the foundation standards.

A concern was expressed about the role of DEA in promoting or inhibiting the adoption of true electronic prescribing. Currently the DEAs lack of specification regarding a legally valid electronic signature is holding Utah back from moving aggressively forward in the area of electronic prescribing except for the use of faxes. Since the proposed rule clearly does not include faxed prescriptions, the DEA may represent a significant obstacle to the wide spread adoption of true electronic prescribing.

The group commented that the problem with the DEAs lack of action is not that Schedule II drugs constitute a significant portion of the prescriptions – they don't. Instead, the problem is that Utah, like most states, wants to develop a *single method* for all electronic prescriptions Until the DEA makes a decision regarding their version of an electronic signature this cannot happen. UHIN recommends that the Secretary encourage the DEA to make a decision and implement their decision prior to the January 2006 implementation date for the MMA foundation standards.

There are no obvious cost savings to provider for e-prescribing; e-prescribing may actually slow providers down (i e., take more time).

What is the incentive to participate in e-prescribing? Participants listed several issues that motivate providers towards adopting e-prescribing:

- Ease of use
- Saving time (go home earlier)
- Reduce staff/physician time on prescription issues
- Younger physicians are more likely to adopt (wait until older physicians retire)

Many EMRs only automate the current manual administrative process; they don't have the capability to manage clinical care. There was general consensus that an e-prescribing tool works much better when integrated into a full EMR.

There was a suggestion that HHS mandate vendors to comply with certain EMR standards.

Comment about:

*More than 8 8 million ADE occur each year in ambulatory care*

*CITL1 estimates that nationwide adoption of e-prescribing would eliminate nearly 2 1 million ADEs per year prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs.*

*E-prescribing would promote efficient and effective use of drugs by ensuring that prescribers have up-to-date information regarding advances in drug therapies*

**Comment:**

These statements were quite controversial. There is very little known about ADEs. There isn't really any good information about the number of ADEs per year or the impact of those ADEs on the health care system. The group was somewhat skeptical about the final bullet that e-Rx would promote efficient and effective use of drugs. More studies are needed before these types of statements can be made with some credibility.

Comment about:

*Improvements, enabled by e-prescribing programs, will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers.*

**Comment:**

There was some question about the clinical impact of e-prescribing (people cited the recent study showing an increase in certain types of errors in CPOE). People were in agreement that e-prescribing would have a positive impact on problems relating to coordination between pharmacies and health providers; that is, it will be relatively easy to sell office managers on e-prescribing if it can be shown that it improves the workflow in the office. However, it still appears to be difficult to sell e-prescribing to physicians, particularly as a stand-alone tool

Comment about:

*Estimate: 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program. Because most health plans/PBMs currently have e-prescribing capability, any additional costs associated with hardware/software connectivity would be minimal. The only expense attributable to health plans are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing. We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs.*

**Comment:**

There was general consensus that this was a valid assessment of the impact on health plans/PBMs. People suggested that health plans/PBMs would bear an additional cost to pay for new transaction costs (e.g., transactions between prescriber and PBM).

Comment about:

*We request comment on our expectation, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. We expect many plans to provide these incentives to prescribers to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. We expect that this will be a transfer of costs from prescribers to health plans, and will neither increase nor decrease the overall impact of implementing an electronic prescription drug program.*

**Comment:**

There was skepticism about whether plans would incur a *substantial* financial benefit from just e-prescribing alone. The true benefits to plans are believed to come when providers utilize full EMRs with clinical data analysis capability. There was general agreement that a stand-alone e-prescribing tool doesn't bring a lot of value to physicians.

Comment about:

*Health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance. We have no basis at this time for estimating the precise timing or magnitude of either gross or net savings. We request public comments and information on this topic that we can utilize when revising this analysis for the final rule*

**Comment:**

There was strong agreement with the statement that "we have no basis at this time for estimating the gross or net savings "

Comment about:

*Estimate: 5 and 18 percent of physicians and other clinicians are using e-prescribing more than 3 billion prescriptions are written annually*

*Estimate: about 203,000 physician office establishments (~88,061 physicians) The decision to adopt e-prescribing probably rests with the group rather than the individual physician.*

*Expect*

*e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, magnitude and timing of savings first will have to be demonstrated to many prescribers to induce them to make the "up front" investment in new systems An additional incentive for prescribers to e-prescribe exists, which is the improved patient care that e-prescribing brings.*

**Comment:**

There was doubt expressed about the economic benefit e-prescribing would bring to providers. Physicians are most likely to adopt e-prescribing because it saves staff time, particularly on refills and renewals. However, it doesn't seem likely to result in any economic benefit *per se*. The best implementation of e-prescribing is within the context of a full EMR. Stand-alone e-prescribing tools bring very limited value particularly since they are often focused on new prescriptions

Comment about:

*We think there are few EMR/e-prescribing vendors are currently using systems that may be in some respects incompatible with these standards We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process We request comments on whether there are some transition costs attributable to these standards and whether there are steps that we could take to mitigate those costs.*

**Comment:**

People did not agree with the comment "We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process " This is not what happened with HIPAA **Vendors usually charged substantially for these upgrades** Most e-prescribing now is via fax **People expect that there will be substantial cost associated with upgrading to the MMA messages.** In addition to the work to simply connect, there is the internal work to create and manage these messages and their associated data bases

**The connectivity will only be effective if providers can connect to a non-profit hub, a RHIO.** Without such connections providers will be forced to either connect to many pharmacies or PBMs or to work with for-profit clearinghouses which have proven to be quite expensive on the administrative side

Comment about:

*The overall costs of buying and installing systems are several factors including--*

*Changing in the business practices of providers' offices.*
*Changing record systems from paper to electronic; and*
*Training staff.*

*Expect costs to be defrayed by incentives*

*We invite comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing.*

*We anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance*

**Comment:**
The group did not see a significant cost savings for prescribers doing e-prescribing. They did envision it as a significant financial investment. The group did see a significant costs savings to pharmacies.

Regarding incentives, third party payers appear to be having mixed reactions to the suggestion that they offer incentives to prescribers for e-prescribing. Perhaps of more interest (more potential cost savings) is the Formulary and Benefits message. One provider with an internal e-prescribing tool in place has 95% formulary compliance right now. They don't' envision much ROI for the MMA rules

There were also questions regarding the impact of e-prescribing on ADEs. The group recommended that further studies be done. Very little is known about ADEs

Comment about:

*Economic benefits that accrue to prescribers that implement e-prescribing*

*A 53 percent reduction in calls from, and a 62 percent reduction in calls to, the pharmacy.*

*Time savings of one hour per nurse and 30 minutes per file clerk per day by streamlining medication management processes.*

*Decreased time spent handling prescription renewal requests.*

*Dramatic time savings that permitted reallocation of nursing and chart room staff*

*Potential reductions in malpractice insurance*

**Comment:**

The group felt that e-prescribing will have different benefits depending on whether it is part of a full EMR or a stand-alone tool. Using a stand-alone e-prescribing tool creates relatively high administrative demands as all the patient information must be entered every time the physician uses the tool to prescribe

People agreed that e-prescribing would result in decreased time in handling prescription renewal requests. However, people felt that the economic benefits e-prescribing for new prescriptions was less certain for physicians

Comment about:

*We are requesting information on these factors to help us improve our analysis for the final rule. Additional examples of administrative savings from e-prescribing, as well as costs of implementing such systems, would be particularly beneficial*

**Comment:**

The primary benefits to a physician on e-prescribing may come with increased formulary and generic prescription compliance. Many payers already have systems in place to reward physicians for this. The priority from a physicians perspective is med-med interactions, med-allergy interactions, and then formulary.

One question regarding formulary compliance is whether the plan has a formulary that is structured to increase compliance and whether it is tiered.

Comment about:

*Reported benefits:*

*Reduced time-consuming phone calls to physicians.*
*Improved accuracy and less time for refill authorizations*
*Additional time available for patient contact and services*
*Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).*
*Improved turnaround time for refill authorizations.*

**Comment:**

Pharmacists agree that e-prescribing would result in reduced time calls to physicians, improved accuracy and less time to handle refills. However, pharmacists would not know if a physician had reviewed the current prescriptions a patient was on through the *Formulary and Benefits* message. Pharmacies do have data bases but only of the prescriptions they have filled. It is suspected that there are many people that use more than one pharmacy, primarily out of convenience

It was noted that while physicians and pharmacies bring up these systems, the refill/renewal process will actually *slow down* until the bugs are worked out and people become comfortable with the new routines

Comment about:

*Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing.*

*Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.*

*The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.*

*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive.*

*We do request additional information on pharmacy impacts.*

**Comment:**

Point 1: The review group had problems with the statement: *Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing.*

Many written prescriptions do not reach the pharmacy. The group *does* expect a material change in the volume of prescriptions that reach the pharmacy to fill. The number of prescriptions *written* may not change, but we expect that the number of prescriptions that *reach pharmacies* may increase dramatically This might pose a challenge to the pharmacies in two ways:

a It might results in an increase in prescriptions that are filled but then not picked up, which then need to be returned to stock (a very labor intensive process)

b. Patients may come to the pharmacy expecting the prescription to be ready 'immediately' because the physician has said "I've sent your prescription to the pharmacy electronically so it will be ready for you to pick up when you arrive there " In a busy pharmacy it may take over 1 hour to fill any prescriptions regardless of its source. It may be important to manage the expectations of patients

Point 2: The review group had problems with the statement: *Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.*

The group does expect that implementing e-prescribing will have a significant negative economic impact on pharmacies, particularly the small independent pharmacies Our experience with HIPAA has clearly demonstrated that pharmacies and physicians are usually charged by the vendor for these types of changes. Small business are often more impacted by these charges.

Point 3: The review group had problems with the statement: *The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.*

The type of networking that pharmacies currently support is pharmacy to PBM. Most e-prescribing now is via fax, not true e-prescribing The MMA rule proposes a new connection: that of pharmacy to prescriber Very few pharmacies are networked to exchange an NCPDP message with a physician; it is a completely different process than faxing prescriptions **Hence, the costs could be considerable, particularly for small independent pharmacies.**

Point 4: The review group had problems with the statement: *Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive.*

Point 4 basically states that adoption will only occur where there is a good business case for it If the business case were so obvious, it would have been adopted much sooner Is it a reasonable

assumption that there will be little/no cost to pharmacies? Probably not It may be voluntary only in the sense that if you do not do it you will go out of business.

Comment about:

*Expected benefits*

*appropriate drug compliance management and Improved medication use,provide information to prevent adverse drug events*

*improve patient safety by detecting various kinds of prescribing errors, duplicate prescriptions; drug-drug, drug-allergy, drug-disease interactions, incorrect dosage strengths prescribed; problems relating to coordination between health care providers and pharmacies*

*Drive physicians to appropriate formulary choices*

**Comment:**

The group did not see how the rule would impact improved medication *use* There did not seem to be any evidence supporting this claim.

From the patient's perspective, most of the benefits are driven by the use of good *decision support* which is tied into data bases on drug-allergy, drug-drug and drug-treatment information. The messages which might most impact the patient are the Fill Status Notification messages The group has concerns about this from two perspectives:

1) Will this bring additional liability to physicians?
2) Will patients view it as a violation of privacy?

The one member of the group who has brought up an e-prescribing system noted that they can be quite effective but *physicians must first put in a lot of time tuning them.* For example, physicians may get bombarded with warnings about drug-drug, or drug-allergy interactions many of which may be irrelevant or unimportant to the particular patient. Each physician sets up rules regarding which warnings will actually be presented. This takes time and effort.

Comment about:

*Nothing in this system creates direct costs for patients*
*We believe that reductions in patient mortality and morbidity would be a substantial benefit resulting from the adoption of e-prescribing, although we are unable at this time to provide quantitative estimates*
*Patient health benefits are likely to far exceed the other categories of benefits and direct costs.*

**Comment:**

While nothing in the rule creates direct costs there will be many indirect costs to patients There will be a cost to patients to subscriber to the MMA Plan D benefits Patients who subscribe to Plan D benefits who are also covered under Medicaid will lose their Medicaid drug benefits (which may not be beneficial to the patient) The group had heard reports that other senior's plans are also going to drop their drug benefits in favor of the Medicare drug benefits; so there will be a cost to patients for participating in this system

The group did not agree with the claim that there will be a reduction in patient mortality and morbidity There are not enough metrics done at this point to make the claim believable

Comment about:

- *Expect:*
  - *Growth of e-prescribing as business potential for healthcare information technology vendors*
  - *Costs associated with e-prescribing and potential business opportunities could be allocated toward new product development.*
- *Question: Impact on entities such as*
  - *pharmaceutical and medical device manufacturers,*
  - *public health organizations,*
  - *research institutions*
  - *academic institutions*
  - *professional lay organizations*
- *We invite public comment on the impact of e-prescribing for these entities.*

**Comment:**

Public Health: the public health potential in this exchange is significant:
Prescription drugs can be used a surrogate measure of several chronic diseases
Pharmacists could send reports to the state's controlled substances data base real time.
Public health will need funding for infrastructure and training to realize this potential.

Research: Research could also benefit significantly as long as patient's privacy is adequately protected

Other entities which will be significantly impacted are rural pharmacies and rural providers, particularly hospitals Rural clinics, (e g , the rural community health centers) often act as the only acute and ambulatory care centers in the community The rule must be structured so that it does not negatively impact these critical facilities

Comment about:

*Approximately 95 percent of pharmacy firms, which account for about 51 percent of pharmacy establishments, are small business (1997 Census data)*

*Estimate that more than 29,000 pharmacy establishments would be considered small entities Includes almost all physicians in private practice*

*Expect*

*proposed rule would have an impact on a substantial number of small businesses due to the percentage of pharmacies and providers that are small businesses. distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale*

*However as many as 75 percent of pharmacies already are conducting e-prescribing and 5 to 18 percent of prescribers are using this technology.*

*This demonstrates that it is economically beneficial.*

*Predict this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required*

*Welcome comments on this conclusion and additional information on the small business effects of this proposed rule.*

**Comment:**
Most of the e-prescribing currently being conducted by pharmacies is fax, not true e-prescribing. **We believe there will be a significant impact on small pharmacies.** The group is not convinced that e-prescribing alone has been shown to have a positive economic benefit for physicians, particularly those in small businesses. 95-82% of physicians are NOT currently using this technology; therefore we believe the economic case has not yet been made on the physician side.

We are unsure what an Initial Regulatory Flexibility Analysis is, but if it could show that small pharmacies and providers, particularly rural pharmacies and providers would be negatively impacted then that should be documented Furthermore, those groups should be protected in the final rule if necessary.

We recommend that small pharmacies and providers who work in under served areas be given special considerations in the implementation of this rule. It is critical that these organizations continue to exist We do not believe this rule has adequately taken their special issues into account.

There was an additional concern about the Formulary and Benefits message. Rural pharmacies do not always have a particular drug on hand Physicians need to be able to says something to the effect that "I am prescribing this particular drug even though it is not on the formulary because it is the only drug available [without driving 100 miles] to this patient in this location "

Comment about:

- *Small rural hospitals*
  - *small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds*
- *Expect*
  - *Proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay*
  - *Proposed rule would not have a significant impact on small rural hospitals because the e-prescribing provisions are both voluntary and cost-beneficial for prescribers*

**Comment:**
Most of Utah's rural hospitals (all except 1 have less than 100 beds) have swing-bed licenses and act as long-term care facilities for the local population. This rule will have an impact on these hospitals because an outpatient care service is a significant percentage of their revenue. As we stated above, the group is not convinced that e-prescribing has a positive economic impact, particularly if implemented in a stand-alone setting (i.e, not as part of a full EMR) Most of these small hospitals do not have anything approaching an EMR

**Submitter :** **Date: 04/05/2005**

**Organization :** **Kaiser Permanente**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Thank you for your consideration of Kaiser Permanente?s views. If you need further information or have questions, you may contact Kristin Bear at 626.405.5963.

**Issues**

Background

Preemption

We encourage CMS to take a more expansive view of federal preemption. The MMA states that provisions promulgated under the MMA preempt any state law that either (a) is contrary to federal standards on e-prescribing promulgated under the MMA or (b) restricts the ability to carry out the e-prescribing provisions of the MMA; and that pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under the MMA. CMS?s proposed interpretation would only preempt state law that is contrary to the MMA standards, not state law that restricts the ability to carry out the purposes of the e-prescribing provisions of the MMA.

Organizations that implement electronic prescribing systems do not adopt two systems: one to comply with federal law and one to comply with state law. Organizations must design systems to comply with the most restrictive standard. Large multi-state organizations must design systems to comply with the most restrictive state standard, resulting not only in financial and administrative burden, but also overall barriers to electronic prescribing. Restrictive state laws that place barriers to electronic prescribing create disincentives to adoption of electronic prescribing programs entirely because organizations cannot create systems that only apply to prescriptions covered by the MMA. If a state law restricts the ability of organizations to implement electronic prescribing under the MMA, then the state statute should be preempted. Where state law stands as an obstacle to accomplishing and executing the full purposes and objectives of Congress, CMS should apply ?implied conflict? preemption to that state law. (See, e.g., Three Affiliated Tribes of Fort Berthold Reservation v. Wold Engineering, 476 U.S. 877 (1986).)

Formulary & Medication History

Kaiser Permanente recommends that any proposed standards for formulary or medication history messaging not be considered as foundation standards to be implemented by January 2006. There is insufficient time for organizations to adopt new technology or modify existing technology to comply with new standards. Adoption in such a short time frame would also be costly and administratively burdensome. Given that standards for these two functions are still in development, Kaiser Permanente recommends that formulary and medication history standards be pilot tested.

Future Standards

Kaiser Permanente recommends that future standards include a standard for electronic signatures, in cooperation with the DEA. We strongly believe that any electronic signature standard must not require Public Key Infrastructure (PKI) technology. Other technology for electronic signatures is more common in existing electronic prescription systems, and any requirement for PKI would impose significant costs on organizations, which would deter adoption of electronic prescribing. A limited requirement for PKI, e.g. for transmission of Schedule II drugs only, does not remedy these concerns. Faced with a choice of adopting potentially cost-prohibitive technology or ?carving out? those prescriptions that require PKI technology for electronic transmission, organizations are likely to maintain paper processes for those prescriptions that would require PKI technology, resulting in a subset of prescriptions that do not benefit from the patient safety and quality of care advancements of electronic prescribing. Other technology for electronic signatures currently in use is secure and reliable in verification of prescriber identity, certainly more secure than currently permitted oral prescriptions, without the unnecessary expense of PKI. Adoption of a standard including PKI would serve as a deterrent to adoption of a complete electronic prescription drug program. Kaiser Permanente recommends that a future standard for electronic signatures be based on the E-SIGN Act definition.

Provisions of the Proposed Regulation

Applicability to Closed Enterprises

Kaiser Permanente strongly agrees with the NCVHS that internal communications within a ?closed enterprise? should be subject to the MMA standards. An integrated organization like Kaiser Permanente, which includes a health plan, pharmacies and a physician medical group in each geographic region where it operates, can implement secure and efficient electronic systems that meet the intent and purpose of the MMA if given the flexibility to do so. Prescription transmissions within a healthcare enterprise can be more easily verified because the enterprise also engages in activities such as credentialing to verify prescribers? licensure and DEA registrations, and utilization review and quality assurance across the enterprise. A closed enterprise can also more closely monitor and enforce the use of security measures, such as use of logon id and password, to better assure the integrity of electronically transmitted prescriptions. Prescribers and dispensers within an organization may also have direct access to Electronic Health Record databases for medical history, medication history, formulary, and eligibility and benefits information. Flexibility in implementation of electronic prescription programs encourages interoperability with EHRs resulting in a more complete electronic system, greater access to information by health care providers, and enhanced patient safety and quality of care.

Further, access to an organization?s own databases should not be considered a ?transmission? of data requiring compliance with these standards. One hallmark of a ?closed enterprise? is a shared health information infrastructure and often shared databases among parts of the enterprise. Access to an organization?s own databases should be outside the scope of the MMA standards.

Requiring organizations to convert their internal systems to MMA standards would not necessarily enhance security of internal transmissions, but would be a

significant administrative burden and cost to the organization, and possibly delay full implementation of an electronic prescription drug program. Organizations that have maximum flexibility to adopt secure electronic systems will be encouraged to expand these systems beyond individual prescribers and medical offices to all parts of the closed enterprise, such as hospitals, skilled nursing facilities, and home health agencies, resulting in better integration of health care information that enables better care.

For consistency, we suggest that CMS adopt a definition of ?closed enterprise? that is similar to the HIPAA definition of ?organized health care arrangement? for purposes of identifying transmissions within an enterprise that would be outside the scope of these rules. Specifically, we suggest that CMS either reference the HIPAA definition of an ?organized health care arrangement? or adopt the following definition:

A ?closed enterprise? is

1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider that share a common electronic health information system;
2. An organized system of health care in which more than one covered entity (as defined by HIPAA) participates and in which the participating covered entities:
a. Hold themselves out to the public as participating in a joint arrangement; and
b. Participate in joint activities that include at least one of the following:
i. Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; or
ii. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; and
c. Share a common electronic health information system

**Submitter :** **Dr. M.Ruiza Yee** **Date: 04/05/2005**

**Organization :** **Dr. M.Ruiza Yee**

**Category :** **Individual**

**Issue Areas/Comments**

**GENERAL**

GENERAL

The effective date for e-prescribing standards should be extended. The final standards formulated may be skewed as it was developed by pharmacy industry members. Also, the standards do not support the Medicare Prescription Drug, Improvement and Modernization Act (MMA) requirements.There should be more pilot testing.

**Submitter :** **Dr. Janis Chester** **Date: 04/05/2005**

**Organization :** **American Association of Practicing Psychiatrists**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

The regulation will put patient privacy at risk by forcing more physicians to become covered entities under HIPAA, and by encouraging the use of unsafe electronic communication systems.

**Issues**

Background

There are two problems with this proposal for electronic prescribing. (1) It forces all physicians who engage in electronic prescribing to become covered entitites under HIPAA and (2) it ignores the fact that nation's electronic information systems are highly vulnerable to hacking and corruption.

With respect to HIPAA, the Amended Privacy Rules allows the release of personal health information without patient consent for the purposes of treatment, payment and health care operations. This is allowed in spite of the fact that the Department of Health and Human Services has noted, 'the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers. More than anything else, the relationship between a patient and a clinician is based on trust.' HIPAA legalizes violation of this trust which is prohibited by professional ethics. Therefore increasing the number of physicians who are covered entities under HIPAA will increase the number of patients who are at risk to have their privacy legally violated.

With respect to the lack of security with the use of electronic prescribing, the findings of the President's Information Technology Advisory Committee show that electronic information systems are highly vulnerable to hacking and corruption, the vulnerabilities are increasing at a rate of 20% a year, and the vulnerabilities cannot addressed without redesigning the information systems from the ground up to build in security measures. 'Cyber Security: A Crisis of Prioritization' (February 28, 2005).

Provisions of the Proposed Regulation

Proposed regulations will increase the number of physicians who are covered entities under HIPAA. This will put patient privacy at risk.

Regulatory Impact Analysis

The regulation will put patient privacy at risk.

Collection of Information Requirements

see above

**Submitter :** **Mr. Elliot Stone** **Date: 04/05/2005**

**Organization :** **Massachusetts Health Data Consortium**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

MHDC convened a meeting of its membership representing providers, pharmacy benefit managers, payers and e-prescribing vendors to coordinate a Massachusetts community response to the NRPM. Please see the attached response which includes the comments made by the group and recommendations on specific issues, as well as factors in lessons learned from the MedsInfo-ED project.

CMS-0011-P-26-Attach-1.DOC

Massachusetts Health Data Consortium, Inc.

# MHDC Response: CMS-0011-P - Electronic Prescribing and the Prescription Drug Program


**SUBMITTED BY**

**Elliot M. Stone, Executive Director and CEO**
**Massachusetts Health Data Consortium**
460 Totten Pond Road, Ste. 385
Waltham, MA 02154

781-890-6040 — www.mahealthdata.org

**CONTACT PERSON**

**Lynne Dunbrack**
**MA-SHARE**

Phone: (508) 276-1040
Email: ldunbrack@mahealthdata.org


## INTRODUCTION

Massachusetts Health Data Consortium (MHDC) welcomes the opportunity to respond to the CMS proposed rules for e-prescribing. Founded in 1978 by the state's major public and private health companies, MHDC's mission is to "lead the development of a comprehensive data system to address the health information needs of the Commonwealth for the purpose of improving health care and health." Massachusetts, long recognized as a world class center of medical excellence, is also recognized for its innovative use of state-of-the-art healthcare IT.

MA-SHARE, LLC was established by MHDC in 2003 as a vehicle to advance the introduction and deployment of clinical data exchange (CDE) in Massachusetts. MedsInfo-ED, a patient safety initiative that makes available patients' dispensed drug history from multiple data sources to emergency department clinicians, is MA-SHARE's first clinical data exchange project. This project is the first step towards the development of an Rx Gateway which will support end-to-end e-prescribing. In addition, MedsInfo-ED helped to identify critical "lessons learned" that could present barriers to successful e-prescribing. These lessons ranged from technical to regulatory to procedural issues; some of which could be easily resolved through existing collaborative efforts while others will require amending current state legislation.

In mid-March, MHDC convened a meeting of its membership representing providers, pharmacy benefit managers, payers and e-prescribing vendors to coordinate a Massachusetts community response to the NRPM. The following response includes the group's comments and recommendations on specific issues, as well as factors in lessons learned from the MedsInfo-ED project.

## BACKGROUND

### Definition of Electronic Media

*Faxed Prescriptions*: The MHDC members discussed whether a prescription that originates electronically from an e-prescribing tool (e.g., EHR, CPOE or stand-alone e-prescribing application) with a computer-generated fax of the prescription sent to the pharmacy that was then printed on paper is an electronic prescription subject to these rules. The group consensus was that dropping a prescription to paper (printing a faxed prescription) is *not* e-prescribing. In addition, there needs to be a standard for the information that is conveyed in a faxed prescription and how it is presented. MHDC recognizes that creating a fax standard is beyond the scope of this Rule. However, we recommend that a committee should be established to explore fax prescription standard formats. A pilot could explore the fax issues and move this issue forward. In the interim, the SureScripts standard for faxed prescriptions could be used as a potential starting point for establishing standards for faxed prescriptions.

### Scope of Preemption, specifically State Preemption

*Restricted Access to Sensitive Medication Information:* Pre-emption of state regulations that limit access to or transmission of prescription information is critical to accelerating the adoption of e-prescribing. For example, federal and Massachusetts state laws restrict access to sensitive drug information that indicates the treatment of AIDS/HIV, mental health disorders and substance abuse. Clinicians need access to a comprehensive medication history, specifically sensitive drug information which might be difficult to accurately ascertain from the patient. The information about these sensitive drugs is particularly important when treating a patient and prescribing other medication, and is directly related to patient safety. Until this restriction is lifted for treatment purposes, sensitive drugs are not included in drug-drug interaction checking (DUR) and clinicians risk prescribing new medications that will have an adverse drug interaction with the patient's current medication regimen. A (more) complete medication history allows clinicians to be proactive versus reactive.

*Cumbersome Consent Processes*: In addition to preventing access, some state regulations impose a consent process that creates a cumbersome, if not impossible, workflow process to obtain real-time access to medication history. Massachusetts state insurance regulations require that additional written consent be obtained in advance before a health plan can release information related to AIDS/HIV treatment, and before indemnity carriers, including Blue Cross Blue Shield, can release information related to mental health treatment. These regulations, enacted before legislators and the healthcare industry envisioned payer data being used for direct patient care in real-time, limit access to the patient's medication history.

*E-Prescriptions for Controlled Substances Not Allowed:* The prohibition of electronic prescriptions for controlled substances (i.e., the requirement of a handwritten or "wet" signature) is another example of a regulatory barrier to e-prescribing. The group estimated that 15 to 20% of prescriptions are for controlled substances. Each time a prescriber is required to write a paper prescription over an electronic prescription, there is a risk that he or she will abandon the electronic e-prescribing solution entirely. The industry needs to explore ways to protect the integrity of prescriptions for controlled substances while allowing them to be electronically transmitted.

*Partial Solutions Thwart Adoption:* Bottom line, any state or federal regulation that engenders a partial solution (e.g., the ability to view a partial medication history or electronically submit certain types of prescriptions) will discourage e-prescribing adoption. Pre-emption of these regulations will address these local regulatory barriers.

## Criteria to Access "Adequate Industry Experience"

While MHDC concurs with the criteria for accessing adequate industry experience, we believe that the relatively low adoption of e-prescribing nationwide warrants conducting a pilot to "test run" the formulary and medication history standards prior to their being named foundation standards. A pilot would help identify areas for improvement, review interoperability, and confirm ability to provide medication history across pharmacy benefit manager data sources.

## Standard Evolving and Setting Process

*Standards Update Process:* The group was concerned that if the standards were modified to accommodate technical changes or correct technical inconsistencies without an open public comment process, that this could be an issue for e-prescribing. MHDC recommends that the standards development organization (SDO) responsible for a standard be the body that determines if an update to the standard is minor, requiring no comment period beyond the normal internal process of the SDO. The experience in adopting changes to the HIPAA transactions for minor corrections has shown that the full Federal rule-making process is cumbersome and results in delays that impede industry use of named standards.

*Drug Identification Schemes:* MHDC also suggests that a coding scheme be adopted for drug identification that can be used for clinical representation. Such a code set could be adopted as a standard through the National Library of Medicine, in the same manner that was used for SNOMED codes. The industry needs to accelerate the development of RxNorm for general distribution. It is imperative that the e-prescribing standards meet the clinical requirements of prescribers.

*Eligibility 270/271 Transaction*: MHDC believes that the industry also needs to focus on the 270/271 Eligibility transaction, which is an essential building block for reliable clinical data exchange. There are still issues with the implementation of the 270/271 eligibility transaction after HIPAA transaction standards went into effect. For example, MedsInfo-ED — MA-SHARE's early-stage clinical data exchange initiative that provides dispensed medication history to ED clinicians — uncovered a difference in interpretation regarding the data used for the 271 response that affected the ability of clinicians to verify patient data from approximate data matches. The 271 response should return demographic data on file with the PBM (i.e., data source being queried) and not simply echo the 270 request data (i.e., original patient search criteria). This is important because some PBMs use probabilistic matching such that Smith and Smythe are considered a match.

Such differences between data entered and data returned need to be displayed for users to identify inexact matches, and inform the requesting clinician of the possibility of a false positive match and data integrity issues, or simply the need to verify the patient and misspelling errors in the search criteria entered. It should be noted that any time a user begins to suspect the veracity of information presented by an e-prescribing application (or any other healthcare information system), the risk of clinician abandonment increases. It is very challenging to turn around a negative perception of a clinical data exchange project.

MHDC recommends that language be included in the Final Rule to help reduce such conflicting interpretations. The language should state that usage clarifications and explanations issued by the authoring body in the standards development organization are to be recognized as normative for the standards named for e-prescribing.

*Avoid Multiple Sets of Standards*: The MHDC members briefly discussed the risk of one set of named standards for Part D beneficiaries and another set for other classes of patients. The general consensus was the industry is not likely to adopt two sets of standards because of the time and expense involved in the standards setting effort. The group felt strongly that only one set of standards be promulgated for all patient classes to help reduce the cost barrier associated with standards compliance, and to encourage e-prescribing adoption by providing a single solution for multiple situations.

*MHDC Recommends Piloting Standards:* Piloting the various named standards provides an opportunity to fully evaluate the standards implementation and make modifications before the standards are widely deployed. RxNorm is still in its nascent stages of development and could use more refinement before it can replace the current (imperfect) drug coding schemes. There may be other, similar 270/271 implementation issues like those identified by the MedsInfo-ED project, that will impact e-prescribing that would be discovered through piloting the named standards. MHDC believes that the relatively low adoption of e-prescribing nationwide warrants conducting a pilot to "test run" the named standards.

### Use of NPI and/or Alternatives

The use of the NPI should not be accelerated for e-prescribing. The group believed that the healthcare industry could not absorb accelerating the NPI; most entities will not be ready before the regulations go into effect May 2007. The industry should continue to use the current numbering scheme for e-prescribing.

### Formulary, Benefit and Medication History Standards

MHDC believes that at the present time, there is no widespread agreement on a single standard for formulary and medication history. However, adoption of such standards should be accelerated and be included as foundation standards. We welcome the suggestion that the RxHub formulary standards be submitted for evaluation and adoption by NCPDP. By seeking broad industry input that includes a focus on the clinical use of these standards, clinically-oriented standards for formulary and medication history can be developed.

Clinicians noted that formulary messages should support the e-prescribing process by alerting clinicians if a drug is off formulary or requires prior authorization by the payer. Marketing messages from pharmaceutical companies promoting one brand of drug over another included in a formulary transaction were perceived to hinder the e-prescribing process and stand in the way of the physician-patient relationship. These types of messages should not be allowed by the standard.

When the standard for medication history is issued, that standard should provide explicitly for all drug information, including sensitive drug information to be reported to a clinician. This provision should preempt any local laws prohibiting such information from being included in medication history.

The healthcare industry should expect that the various stakeholders will collaborate to establish standards that will best suit the clinical requirements of prescribers. A concurrent pilot of proposed standards will assist in developing and refining appropriate standards. Such pilots can be readily undertaken in Massachusetts. Rx Gateway, MA-SHARE's next clinical data exchange project, will support end-to-end e-prescribing including checking for formulary compliance and drug-drug interaction by obtaining access to medication history.

## PROVISIONS

### Use Standards within the Enterprise

MHDC urges that there be no requirement for enterprises to use standard e-prescribing transactions when the data is exchanged within the enterprise. While organizations with

large closed systems may easily adopt the named standards for internal use, other organizations should not be required to modify internal systems. We believe that there would be no benefit to patient care or ease of use in requiring the named standards to be used for internal data exchange. In addition, requiring remediation of internal transaction systems could be unnecessarily expensive for enterprises, and further discourage e-prescribing adoption.

## IMPACT ANALYSIS

### Health Plan e-Prescribing Incentive Programs Impacts on Plans and Providers

MHDC would like to underscore that incentives, either by rule or other inducements, be put in place to encourage prescribers to implement e-prescribing tools. Since the Rule does not mandate that e-prescribing be adopted, health plans, pharmacy benefit managers, dispensers, and other entities may incur large costs to implement with little usage. In the interest of patient safety as well as administrative savings, universal adoption should be encouraged and accelerated.

## GENERAL COMMENTS

### Suggestions for Improvements

*Privacy and the Minimum Necessary Information Requirement*: MHDC acknowledges that while the Rule needs to address privacy concerns, electronic prescriptions should not be subject to the administrative burdens imposed by HIPAA. Specifically, all data sent in the SCRIPT transaction, even if marked optional in the standard, is "necessary" for the prescription process and is information exchanged between covered entities for treatment purposes. Therefore, the Rule should state that all data in the SCRIPT messages named under this Rule are considered to meet the Privacy standard of the minimum necessary information and no additional document is required by covered entities when the transactions are exchanged between covered entities.

*Electronic vs. Digital Signatures:* The group consensus was that there is not enough industry experience with public key infrastructure (PKI) technology to use digital signatures for e-prescribing, especially at the individual prescriber level. Furthermore, PKI requires significant administrative overhead to establish and maintain digital signatures. MHDC recommends that the electronic signature from faxed document is sufficient for faxed prescriptions, and an equivalent authentication process other than PKI be established for end-to-end e-prescribing.

**Submitter :** **Mr. Gregory Weishar** **Date: 04/05/2005**

**Organization :** **PharmaCare**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Attachment.

Regulatory Impact Analysis

See Attachment.

Collection of Information Requirements

See Attachment.

Provisions of the Proposed Regulation

See Attachment.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

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**Submitter :** **Mr. Brian Bamberger** **Date: 04/05/2005**

**Organization :** **MediMedia USA, Inc**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-0011-P-28-Attach-1.DOC

April 4, 2005

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

***Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments***

Dear Centers for Medicare and Medicaid Services:

MediMedia appreciates the opportunity to comment on the Medicare Prescription Drug Benefit notice of proposed rule-making (NPRM).

MediMedia Information Technologies is a division of MediMedia USA, a $250 million publishing company. One of the world's leading providers of healthcare communication, educational materials and services, MediMedia is an *independent* international company with a reputation for the quality and innovation of its products, and the strength of its truly global representation.

We own and distribute the InfoScan Formulary Database, which contains more than 3,400 health plan, PBM, PPO and self-insured employer formularies. In addition to most of the plans associated with Rx Hub and CAQH, we represent many of the smaller plans and PBMs who have thus far chosen not to affiliate with those organizations.

We have been providing a formulary database to electronic health records (EHR), computerized physician order entry (CPOE) and ePrescribing software companies since 1994. Our clients include WebMD's Medical Manager, GE Medical's MedicaLogic, Cerner, NextGen, Misys and others – a veritable a "who's who" of mature health care information technology providers.

**I. Background (F. R. page 6257)**

***2. State Preemption (F.R. page 6259)***

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**MediMedia Recommendations:**

Our president, Brian Bamberger, was on the task group that responded to the NPRM on behalf of NCPDP. We agree with NCPDP's comments on preemption.

**E. Current E-Prescribing Environment (F.R. page 6260)**

**MediMedia Recommendations:**
We agree that E-prescribing is a complex process, and that there are different levels of technology. A possible misperception is that most technology solutions have the ability to perform patient eligibility checks. In reality, most do not.

There are many challenges associated with eligibility checking. On the physician software side (ePrescribing, EHRs and CPOE systems), there is a larger percentage than we believe CMS realizes that are legacy systems and do not have electronic connectivity outside the group practice or enterprise setting. Upgrades have been slower than expected because of the costs.

Systems that have electronic connectivity have just two choices today: (1) RxHub or (2) direct to a health plan or PBM. While plans and PBMs are proficient at eligibility checking in the claims world, many are not yet ready to transmit information that would accommodate linking to formulary and benefit information. Of note, *only two of the three RxHub founders* provide eligibility information.

The way the majority of prescribers link to formulary is as follows: the ePrescribing, EHR or CPOE system demographic information – including health plan – from the practice management system (PMS). The pre-loaded formulary has a plan name. When the formulary plan name and the plan name coming from the PMS match, the prescriber is linked to the formulary. The prescriber isn't aware of any of this, as it all takes place behind the scenes.

We think that it is important that CMS understands this prior to moving forward with the Part D program. We describe the best way to address this later in our NPRM response. In summary, we recommend that PDPs be required to provide a formulary identifier on their benefit cards.

**(F.R. page 6263)**
*We propose the following critical characteristics for formulary and benefit data standards:*

**MediMedia Recommendations:**
Even though we have greater marketshare than RxHub, we were willing to work with them to enhance their proprietary formats to make a contribution to the marketplace. As the proposed formulary & benefits standard moves through the NCPDP accreditation process, we continue our support. We think that the combination of the industry experience gained from RxHub proprietary formats and collaboration of different stakeholders meets the characteristics that are critical to becoming a formulary standard.

That said, we do think there are components of the formulary and benefits formats that are redundant, such as the preferred alternatives list.

We are also not comfortable with the proposed standard's treatment of prior authorization. For example, while each drug has a 100- and 200-character text field, the resource link is at the benefit level. We believe that it should be available at the drug level so that a link to prior authorization information can be provided.

For very appropriate reasons, many fields are optional (conditional). We agree with this approach so that plans can have maximal flexibility. However, for CMS to extract the greatest benefit from the formulary & benefit standards, we recommend that CMS require its PDPs to provide specific information.

One example that would provide value to CMS and prescribers is prior authorization. When a PDP requires prior authorization of a medication, the PDP should be required to provide an indication -- a flag -- through the formulary and benefit standard so that the prescriber understands that a pre-authorization request is required. Nearly as important are notes that provide a sense of PDP's rules, and the previously mentioned resource link. In our experience, if CMS does not require PDPs to 1) make available a flag, 2) summarize rules in the form of notes and 3) supply a URL link to prior authorization plans, only a small percentage of them will provide this information.

#### H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

*• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

**MediMedia Recommendations:**

We support the proposed foundation standards without pilot testing.

### II. Provisions of the Proposed Regulation (F.R. Page 6264)

#### C. Proposed Requirements for Part D Plans (F.R. Page 6265)

**(F.R. Page 6265)**

*We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.*

**MediMedia Recommendations:**

While we support NCPDP SCRIPT as a foundation standard, we agree with CMS's proposed exception of not requiring SCRIPT within the enterprise. As noted in the preamble, our clients tend to be the "who's who" of clinical software companies, many of which are enterprise systems' vendors. As such, we believe we have a handle on ePrescribing in the enterprise environment.

**2. Eligibility (F.R. Page 6266)**

*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

**MediMedia Recommendations:**

As we noted in Background, E. Current E-Prescribing Environment (F.R. page 6260), eligibility transactions are not common in ePrescribing. The largest volume of eligibility checks for linking patient to formulary is through RxHub, and there are also some eligibility transactions that go directly to some plans. However, not every plan or PBM wants to go through RxHub for many reasons. Some are concerned for competitive reasons. Others are not ready to take on the costs. Still others are apprehensive of an entity gaining that kind of leverage.

In general, physicians utilizing ePerscribing, CPOE and EHR software applications that do not connect to RxHub have had an exceedingly difficult time identifying a patient's formulary.

To facilitate linking the formulary to the patient, we recommend that the "issuer field" on the NCPDP's "Pharmacy ID Card Standard" include an ability to include a formulary identifier, and that CMS require its PDPs to use it for this purpose.

The field is available to describe the issuer and we recommend than an issuer be required to have an identifier for each formulary being offered. Using this field to identify not only a health plan but the specific formulary the patient is using would allow physicians to quickly identify the list of drugs being used for the formulary including preferred, non-preferred, prior authorized and prescribing limitations from third party databases such as ours.

**I. Conclusions and Alternatives Considered (F.R. Page 6272)**

*We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

**MediMedia Recommendations:**

Requiring the eligibility transaction without requiring the formulary indicator on the pharmacy ID card will have the unintended consequence of either forcing all ePrescribing players to go through RxHub or another not-as-yet established player. The impact of this on PDPs will be substantial, and may not be in the best interest of the industry.

In the absence of the standardized ability to adjudicate prior authorization electronically, the formulary and benefit standard should be modified to accommodate prior authorization information, and PDPs should be required to provide a (1) prior authorization flag, (2) summary of rules and (3) URL linking the prescriber to the plan's prior authorization forms.

Sincerely,

Brian Bamberger, President
MediMedia Information Technologies.

**Submitter :** **Mr. Robert Marotta** **Date: 04/05/2005**

**Organization :** **WebMD Corporation**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Attachment

Provisions of the Proposed Regulation

See Attachment

Regulatory Impact Analysis

See Attachment

CMS-0011-P-29-Attach-1.DOC

WebMD Corporation
Capitol Square
Suite 1800
65 East State Street
Columbus, OH 43215-4294
Phone 614.462.5435
www.webmd.com

April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: **CMS-0011-P**
PO Box 8014
Baltimore, MD 21244-8014

*Re: Comments of WebMD Corporation regarding 42 CFR Part 423; Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule*

To Whom It May Concern:

WebMD Corporation ("WebMD") commends the Centers for Medicare and Medicaid Services ("CMS") for its leadership in convening health care industry stakeholders in the effort to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("MMA"). In this regard, WebMD welcomes the opportunity to respond to certain provisions of the proposed rule.

By way of introductory background, WebMD is comprised of three business units, each of which is a national leader in providing health care information services and technology solutions for participants across the health care continuum:

- WebMD Health, with more than 20 million visitors a month, is the nation's leading consumer-focused health care information Web site. WebMD Health is also the leading provider of personalized, co-branded health and benefit management web sites for use by approximately 15 million beneficiaries of large corporations and health plans. These websites enable consumers to become more educated and pro-active in choosing health plans, treatments, and care providers. Additionally, WebMD Health's Medscape service is the leading destination on the Web for physicians and other health professionals. The site has over 500,000 physician visits per month and, in 2004, Medscape members completed more than 800,000 CME credit hours making Medscape the leading online source for continuing professional education.

- WebMD Business Services is the health care industry's leading clearinghouse for electronic health care transactions, processing over 2 billion transactions per year. More than 300,000 medical and dental providers, 5,000 hospitals, 36,000 pharmacies and

laboratories and 600 information system software vendors rely on WebMD Business Services to connect to nearly 1,200 commercial and governmental health care plans.

- WebMD Practice Services is the leading national provider of integrated physician practice and clinical management systems, supporting thousands of practices sites nationally.

Due to the nature and scope of these operations, WebMD is committed to promoting the development and adoption of interoperable health care information services and technology solutions, including the adoption of standards for electronic prescriptions. Accordingly, WebMD supports and participates in the activities of the eHealth Initiative and such standards development organizations as ASCX12, Healthcare Information and Management Systems Society ("HIMSS"), HL7, NCPDP and other national and state organizations to promote electronic data interchange. Given its connectivity infrastructure and the extent of its installed electronic health technologies, WebMD is committed to working with CMS toward achieving the adoption of standards for an electronic prescription drug program under Title I of the MMA.

## General Comments

WebMD supports the adoption of the definitions proposed at 42 CFR 423.159(a) and the "foundation" standards (*i.e.*, standards for which pilot testing is not required) proposed at 42 CFR 423.160, to include:

- NCPDP SCRIPT Standard, Version 5.0, as delimited, for communicating a prescription or prescription-related information between prescribers and dispensers.

- ASC X12N 270/271, Health Care Eligibility Benefit Inquiry and Response, for transmitting eligibility inquiries and responses between prescribers and Part D sponsors.

- NCPDP Telecommunication Standard Guide, for transmitting eligibility inquiries and responses between dispensers and Part D sponsors.

## Specific Comments

### *I. Background* [*FR*, 6256]

#### *A. Statutory Basis* [*FR*, 6256-6259]

- Electronic Media [*FR* 6257]

WebMD does not object to the proposed use of the definition of electronic media found at 45 CFR 160.103 to determine when a prescriber is electronically transmitting prescription information in a manner that must comply with the proposed standards for an electronic

prescription drug program under the MMA, which amended Title XVIII of the Social Security Act ("Act").

***2. State Preemption*** [*FR*, 6258-6259]

Based on a close reading of the MMA, WebMD concurs with the Department of Health and Human Services' ("HHS") proposed interpretation that the preemption provision of Section 1860D-4(e)(5) of the Act has effect only with respect to prescriptions and prescription-related information for covered Part D drugs prescribed for Part D eligible individuals that are transmitted electronically under the MMA's e-prescribing program. However, WebMD believes that the preemption provision, even if narrowly interpreted, will still have the practical effect of establishing "field preemption." WebMD submits that the effect of establishing e-prescribing standards for the Medicare Part D drug program will be comparable to the impact of the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90") on state pharmacy laws and regulations.

In brief, OBRA 90 amended Medicaid to require pharmacists (a) to obtain, record and maintain individual patient profile information for Medicaid beneficiaries, (b) to perform prospective drug utilization review before filling prescriptions for Medicaid beneficiaries, and (c) to offer to discuss the unique drug therapy regime of each Medicaid patient when filling their prescriptions. To comply with OBRA 90 and, more importantly, to rationalize practice standards, the States amended their respective pharmacy laws and regulations to require pharmacists to provide the mandated services not only to Medicaid beneficiaries but also to all patients, regardless of payment source.

In sum, WebMD believes that, even in the absence of HHS broadly interpreting the MMA's preemption provision, state policy makers, with few exceptions, will not require dispensing pharmacists to comply with one set of e-prescribing requirements for Medicare Part D individuals and another set of requirements for the rest of the population. At the same time, WebMD would not suggest that the process of bringing state e-prescribing laws into conformity with the standards established under the MMA will be seamless, timely or transparent. The e-prescribing industry will continue to face many tests and challenges in complying with applicable state law.

The first test of the practicality of HHS' proposed interpretation of the MMA's preemption provision will be how states react to the e-prescribing definition proposed at 42 CFR 423.159(a):

> *E-prescribing* means the transmission, using electronic media, of prescription or prescription related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.

WebMD is not aware of a single state that has adopted an "e-prescribing" definition as broad as the one HHS has proposed. More importantly, WebMD has identified at least fourteen

states that specifically require electronic prescriptions to be transmitted directly to the pharmacy, with no intervening person having access to the prescription.[1] Historically, the vast majority of such prohibitions were adopted to ensure that pharmacy benefit managers did not gain access to prescriptions electronically transmitted between prescribers and pharmacies for purposes of either "steering" prescriptions to mail service pharmacies or initiating therapeutic substitution activities. While direct transmission requirements would not affect prescriptions transmitted directly over the public telephone network, these requirements, applied literally, prohibit the use of e-prescribing networks to route prescriptions from prescribers to pharmacies, to ensure that prescriptions contain all information required by law in the proper format, or to maintain a copy of a prescription transaction for transmission receipt audit purposes.

WebMD urges HHS to prepare to undertake an educational campaign in cooperation with the National Association of Boards of Pharmacy to educate policy makers at the state level of the implications of the e-prescribing standards adopted under the Medicare Part D drug program.

***C. Standards Design Criteria*** [*FR* 6260]

Section 1860D-4(e)(3)(C) of the Act specifies that e-prescribing standards be designed so that they (a) do not impose an unreasonable administrative burden on prescribers and dispensers; (b) are compatible with standards established under Part C of Title XI, standards established under Section 1860D-4(b)(2)(B)(i) of the Act and general health information technology standards, and (c) permit the electronic exchange of drug labeling and drug listing information (RxNorm) maintained by the Food and Drug Administration ("FDA") and the National Library of Medicine ("NLM").

WebMD relies on the products of two commercial database vendors for the drug labeling and drug listing needs of its e-prescribing products—First Databank and Wolters Sklewer. Both vendors have advised WebMD of a concern that RxNorm may be incomplete.

WebMD suggests that, prior to implementing the RxNorm mandate, HHS should ensure that RxNorm's content is validated for completeness. Further, HHS should ensure that the NLM develop a translation table between RxNorm and the commercial database publishers. Such an approach would enable the point-of-care e-prescribing software community to achieve the goal of normalizing drug labeling and drug naming while avoiding the costly process of redesigning existing systems that interface with commercial databases to interface with RxNorm.

***F. Evolution and Implementation of an Electronic Prescription Drug Program.*** [*FR* 6261]

The MMA establishes a timeline for adopting the standards required by the Act to implement the e-prescribing program requirements under Medicare Part D. Section 1860D-

[1]Arkansas, Delaware, Georgia, Hawaii, Iowa, Kansas, Massachusetts, Michigan, Mississippi, Montana, Virginia, Washington, West Virginia and Wyoming. Additionally, in June 2004, the Pennsylvania Board of Pharmacy proposed rules that would prohibit any intervening person from having access to an electronically transmitted prescription. The Pennsylvania rule making is now pending.

4(e)(4)(A) of the Act requires the Secretary to adopt initial, uniform e-prescribing standards no later than September 1, 2005. Section 1860D-4(e)(4)(C)(i) requires the Secretary to conduct a pilot project to test the initial standards between January 1, 2006 and December 31, 2006. However, Section 1860D-4(e)(4)(C)(ii) does not require pilot testing for any initial standard for which there is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. Further, the Act requires the Secretary to conduct an evaluation of the pilot project and submit a report on the evaluation to Congress not later than April 1, 2007. Finally, Section 1860D-4(e)(4)(D) requires the Secretary to promulgate final standards not later than April 1, 2008.

At 70 FR 6261, HHS explains its criteria for identifying those standards for which pilot testing would not be required (*i.e.*, "foundation" standards for which there is "adequate industry experience") and invites comment not only the criteria but also on (a) how to establish a process to evolve the proposed foundation standards and additional standards (b) how to determine an appropriate implementation sequence that is consistent with the Administrative Procedures Act and other legal requirements, and (c) the role of standard setting organizations and the National Committee on Vital and Health Statistics ("NCVHS").

WebMD believes that the criteria proposed by HHS for determining "adequate industry experience" for the purpose of identifying and adopting those standards for which pilot testing will not be required pursuant to Section 1860D-4(e)(4)(C)(ii) are appropriate and defensible. The criteria include the following:

- The standard is American National Standards Institute ("ANSI") accredited.
- The standard has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner.
- Key industry stakeholders have recognized the standard as the industry standard.

WebMD also believes that the criteria reflect and support the critically important role of ANSI-accredited standard-setting organizations in producing appropriate standards for the MMA e-prescribing program. WebMD would also note that the NCVHS process established by the Act has amply demonstrated that standard settings organizations, particularly the National Council for Prescription Drug Programs ("NCPDP"), are responsive to industry and governmental recommendations. Moreover, the criteria outlined above preserve NCPDP's ability—as a voluntary, consensus-based organization—to balance the recommendations of e-prescribing software vendors, the pharmacy industry, prescribers and NCVHS.

***G. Electronic Prescription Drug Program.*** [*FR* 6261]

HHS has requested comment on three proposed standards to support the Medicare Part D e-prescribing program: provider and dispenser identifiers; formulary and medication history;

and medical history transmission. HHS has also requested public comment on any other standards that should be considered for adoption that do not appear on the chart at 70 FR 6262.

- Proposed Use of the National Provider Identifier ("NPI") [FR 6262-6263]

HHS proposes at 70 FR 6262-6263 to adopt the NPI as the primary identifier for dispensers and providers for the e-prescribing program under Medicare Part D because it is the standard that covered entities will be required to use under The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). However, HHS notes that it may not have the capacity to issue NPIs to all covered providers by January 1, 2006, the effective date of the Medicare Part D drug program. HHS also notes that NCVHS has recommended that HHS allow the use of the NCPDP Provider Identifier Number for dispensers and the NCPDP HCIdea® for prescribers in the event that the NPI cannot enumerate covered providers in time for implementing the e-prescribing program under Medicare Part D.

WebMD supports the use of the NPI for Medicare Part D e-prescribing transactions, once it becomes available. In the interim, WebMD supports the use of the NCPDP Provider Identifier Number for dispensers. For prescribers, however, WebMD strongly recommends the use of Drug Enforcement Agency ("DEA") registration numbers until the NPI is available. While the DEA may not approve, virtually every payor, every e-prescribing software vendor, and every pharmacy system currently uses DEA numbers to identify prescribers. Conversely, NCPDP HCIdea® is not a complete database, and it has not been widely adopted by stakeholders. Moreover, both prescriber and pharmacy systems would require modification to support the use of NCPDP HCIdea®. Because systems will eventually have to be modified to support the NPI, it would be costly and shortsighted to require systems to be modified twice to accommodate the NCVHS interim proposal.

- Formulary and Medication History Standards [FR 6263-6264]

WebMD supports the adoption of RxHub's formulary and medication history standards by the NCPDP. Once these standards have been recognized by the NCPDP and ANSI-accredited, we support their adoption for formulary, benefit and medication history messaging as foundation standards.

- Medical History Transmission Standards [FR 6264]

WebMD understands that HHS is not statutorily authorized to propose or adopt standards for the transmission of a patient's medical history until after the Secretary adopts final standards for the Medicare Part D e-prescribing program. The delay is appropriate because such standards will necessarily have to comply not only with HIPAA privacy and security requirements but also with the interoperability standards envisioned by the establishment of a National Health Information Network facilitated by HHS' Office of the National Coordinator for Health Information Technology.

In addition to the three standards addressed above, WebMD respectfully urges HHS to adopt a standard that provides guidance regarding how a prescriber's drug product selection instructions may be communicated in an electronically transmitted prescription under the Medicare Part D drug program.

- Standard for Communicating Prescribers' Drug Product Selection Instructions.

With a few exceptions, state pharmacy laws do not provide specific guidance for how prescribers' drug product selection instructions are communicated in electronically transmitted prescriptions, whether transmitted computer-to-computer or computer-to-facsimile machine. Clearly, the existing requirements for written prescriptions cannot be applied to electronic prescriptions. Where handwritten signatures and/or handwritten instructions are required, applicable electronic commerce law[2] makes such requirements unenforceable. Further, even though bit-mapping technology can be used to replicate handwritten signatures and instructions (to include handwritten initials, check marks, and abbreviations), few, if any, vendors employ technology that meets the implicit requirement that such handwriting be created contemporaneously with the creation of the prescription. Finally, bit-mapping technology cannot be employed in electronic prescriptions transmitted computer-to-computer because the SCRIPT standard format does not support graphical images.[3]

Additionally, state pharmacy laws require a wide variety of terminology and formats to communicate drug product selection instructions. With respect to the former, for example, the following phrases are required among the states: "Do Not Substitute"; "No Drug Product Selection"; "NDPS"; "Dispense as Written"; "DAW"; "Brand Necessary"; "Brand Medically Necessary"; "Medically Necessary"; and "May Not Substitute." With respect to the latter, some states have also required two, discretely labeled signature lines or boxes of a specific size with labeling requirements in or on which prescribers are expected to insert a check mark, an abbreviation, or their signatures in their own handwriting.

In sum, requiring electronically transmitted prescriptions to comply with the same requirements for communicating drug product selection instructions in written prescriptions is neither reasonable nor enforceable. To accommodate the requirements of electronic commerce law and the limitations of electronic prescribing technology, HHS should adopt standards to provide specific guidance to pharmacists on how drug product selection instructions may be separately addressed in electronically transmitted prescriptions.

The SCRIPT standard provides such guidance for computer-to-computer transmissions. For prescriptions that are electronically transmitted between the prescriber's computer and the pharmacy's facsimile machine, however, WebMD respectfully recommends that HHS adopt a

[2] The Uniform Electronic Transactions Act, which has been adopted by 45 states and the District of Columbia, and the Electronic Signatures in Global and National Commerce Act, 15 U.S.C. §§7001-7006, 7021, and 7031.

[3] In prescriptions formatted according to the SCRIPT standard, drug product selection instructions are transmitted as numeric values: "Ø" for substitution permitted and "1" for substitution not allowed by prescriber. See SCRIPT Standard Format Implementation Guide, Version 5.0 (May, 2004).

separate standard for communicating the prescriber's drug product selection instructions. WebMD would support a standard that would require the inclusion in the prescription of the phrase "Brand Necessary" or any other mechanism that clearly indicates the prescriber's intent to prohibit drug product selection.

***H. Summary of Status of Standards for an Electronic Prescription Drug Program.*** [FR 6264]

WebMD believes that HHS has adopted a sound strategy for phasing in the implementation of a Medicare Part D e-prescribing program. Indeed, given the strict timeline imposed by the Act for the adoption of e-prescribing standards and the criteria HHS has proposed for identifying foundation standards, the standards proposed in the current rulemaking are the only standards HHS could possibly adopt prior to the January 1, 2006, the effective date of the Medicare Part D drug program.

WebMD also concurs with HHS with respect to the strategy the agency envisions for ensuring that future standards (to include DUR, dosage adjustment, and the availability of lower cost therapeutic alternatives) are interoperable with emerging standards for Electronic Health Records ("EHR"). Further, by adopting foundation standards that are ANSI-accredited and have industry experience, the HHS strategy will facilitate interoperability with later industry-adopted standards for EHRs, across software and hardware products. WebMD is active in several organizations involved with the development of EHR standards, including HL7, and will work to ensure that the interoperability goals are achieved.

## *II. Provisions of the Proposed Regulation.* [FR 6264]

***B. Proposed Definitions.*** [FR 6265]

WebMD commends HHS for incorporating the definition of "electronic media," as found in 45 CFR 160.103, into the proposed definition for "e-prescribing." As a result, the proposed definition not only supports the most common means of electronically transmitting a prescription but it also ensures that prescribers will be able to transmit prescriptions electronically to virtually every pharmacy in the U.S. under the Medicare Part D e-prescribing program.

For example, prescribers using WebMD's e-prescribing software electronically transmit some 200,000 prescriptions per month. All such prescriptions are formatted in the SCRIPT standard and transmitted via an e-prescribing network to the pharmacy specified by the patient. However, 63% of these prescriptions are destined for pharmacies that are not technologically capable of receiving a SCRIPT-formatted prescription. As a result, the original SCRIPT-formatted content of the prescription must be reformatted at the network into a graphical image so that the pharmacy's facsimile machine can receive it via a point-to-point transmission over telephone lines.

WebMD would note that other e-prescribing software vendors have taken slightly different but equally compliant approaches to transmitting computer-to-facsimile prescription

transactions. In all such transmissions, the common element is that the electronic prescription never takes physical form in the prescriber's office prior to transmission.

***C. Proposed Requirements for Part D Plans.*** [FR 6265]

HHS requests comment on whether Part D plans should be required to use the standards for e-prescribing transactions within their respective enterprises. WebMD believes that, consistent with the goal of achieving national interoperability for health information transactions, it is essential for all covered parties to support a single standard for prescription transactions: the NCPDP Script Standard.

Recognizing that many Part D plans have already invested significant funds to enable HL7 messaging for e-prescription transactions within their enterprises, WebMD recommends that such Part D plans be grandfathered in at the time of adoption of final standards, provided that the data in such systems is available for interchange with external systems in the required format. Part D plans that implement e-prescribing systems within their enterprises after the adoption of final Medicare Part D e-prescribing standards should be required to comply with the SCRIPT Standard.

***E. Proposed Standards.***

As noted above, WebMD believes that the proposed standards for prescriptions and eligibility transactions meet the criteria of being ANSI-accredited standards for which there is adequate industry experience. Accordingly, WebMD supports their adoption as foundation standards in the proposed regulation and concurs that entities with e-prescribing programs should be required to comply with such foundation standards, if adopted, by January 1, 2006.

***1. Prescription***. [FR 6265]

Concerning the proposed adoption of a foundation standard for the transmission of prescription and prescription-related information, HHS has proposed adoption of all SCRIPT Standard transactions (*i.e.*, business processes) save for the Prescription Fill Status Notification Transaction and its three business cases, on the ground that the latter set of transactions lack adequate industry experience, based on testimony before the NCVHS. WebMD concurs and therefore supports the adoption of the limited set of SCRIPT Standard transactions. Further, WebMD believes that the NCPDP transactions that HHS has identified as ancillary messaging and administrative transactions do not require pilot testing.

***IV. Regulatory Impact Analysis.*** [FR 6268]

***A. Overall Impact.*** [FR 6268-6269]

WebMD believes that, while the adoption of e-prescribing standards by HHS will provide critical guidance to the software industry, such standards will do little or nothing to spur physician adoption of e-prescribing practices. WebMD's experience, to date, is that less than 5%

of active clinicians are using e-prescribing software products. While the number of e-prescribers has dramatically increased in the last 18 months, this increase is primarily due to physician adoption of integrated EHR systems. In an integrated EHR, the e-prescribing module is a component of the full system, and the prescription writing process becomes a critical component of the workflow of patient treatment.

WebMD believes that, to achieve higher than the modest 10% annual growth that HHS predicts, cost savings experienced by other stakeholders must be shared. The organizations achieving the most dramatic cost savings are the payors, through better drug regimen compliance, improved patient outcomes, fewer adverse drug events and hospitalizations, better utilization management, and increased generic substitution.

Based on WebMD's field experience marketing e-prescribing systems, WebMD has concluded that, at best, prescribers view creating and issuing prescriptions electronically as time and cost-neutral within the patient treatment process. They believe this instinctively, in spite of data to suggest that, even if it takes a few more seconds to issue a prescription electronically, the savings in deferred phone calls is substantial. Prescribers believe that since health plans, among all stakeholders, stand to accrue the largest share of the financial benefits derived for the adoption of e-prescribing practices, these organizations should provide compensation to prescribers who adopt e-prescribing practices.

While prescribers are primarily concerned with patient health and safety, they are also small business owners. Accordingly, they are averse to discretionary investments that do not yield a return on investment. WebMD believes that "pay for use" is necessary to dramatically increase physician adoption of e-prescribing practices.

WebMD also believes that other incentives, such as payments to subsidize the costs of hardware and software, while well intended, are misguided. Without an ongoing revenue model, prescribers will take advantage of "one time" incentives but have no commitment to utilize the technology going forward.

***D. Impact on Pharmacies and Other Dispensers.*** [FR 6271]

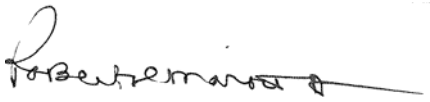
Based on marketplace experience, WebMD does not believe that 75% of the 57,208 pharmacies in the U.S. are online and receiving SCRIPT-formatted prescriptions. Although a substantial number of pharmacies have signed contracts with e-prescribing networks, and while some chain drug store operations are nominally EDI-capable, the number of pharmacies that are actually receiving computer-to-computer prescription transactions is much smaller. For example, WebMD provides e-prescribing systems to prescribers in 39 states. Of the 200,000 prescriptions these prescribers transmit electronically each month, 63% must be re-formatted from SCRIPT for transmittal to the pharmacy's facsimile machine.

WebMD believes that, as the number of prescribers who issue prescriptions electronically grows, more pharmacies will enable SCRIPT-compliant technology because it is operationally more efficient than computer-to-facsimile transactions and, more importantly, it enables

electronic prescription refill transactions. While WebMD believes that the pharmacy industry is committed to embracing SCRIPT-compliant prescription transactions, HHS should not underestimate the costs, logistics, and training required to migrate to that capability. However, as noted above, the proposed "e-prescribing" definition ensures that electronically transmitted prescriptions under the Medicare Part D drug program can be delivered for the foreseeable future to virtually every pharmacy in the U.S. with little or no additional expense to the pharmacy industry.

If you have any questions regarding this matter, or desire further clarification or information, please contact me.

Respectfully submitted,



Robert D. Marotta
Senior Vice President

**Submitter :** **Ms. Kristin Lewis** **Date: 04/05/2005**

**Organization :** **Tufts Associated Health Plan**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Due to work required and cost to update e-prescribing systems and applications, we recommend that there be a clear review process for any proposed changes to the standards and that all parties be given at least one year to accommodate and implement any changes to the e-prescribing standards.

**Issues**

Background

Standard Evolving and Setting Process. In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. CMS invites comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. Specifically, CMS invites comment regarding the role of industry standard setting organizations and the NCVHS.

**Submitter :** **Ms. Kristin Lewis** **Date: 04/05/2005**

**Organization :** **Tufts Associated Health Maintenance Organization**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Foundation standards should not include marketing messages from pharmaceutical companies promoting one brand of drug over another included in a formulary transaction.

**Issues**

Background

Formulary, Benefit and Medication History Standards. CMS sets out the characteristics the Agency will consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicits comments on those characteristics. CMS further solicits comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards.

**Submitter :** Ms. Kathryn Kuhmerker **Date:** 04/05/2005

**Organization :** NYS Department of Health

**Category :** State Government

**Issue Areas/Comments**

**GENERAL**

GENERAL

Other Comments

Federal Medicaid law mandates that a prescriber certify in their own handwriting that a brand-name drug is medically necessary for a particular recipient. NYS has several means to promote the dispensing of generic drugs. For example, the NYS Board of Pharmacy mandates generic substitution for prescriptions filled in NYS and the NYS Medicaid program also requires prior authorization for a brand-name drug when a generic equivalent is available.

Prescribing for Medicare recipients with dual-eligible status, for secondary billing purposes, would still need to meet the above Medicaid program's 'brand medically necessary' requirements. As CMS has oversight over both the Medicare and Medicaid programs, clear guidance is needed from CMS to all state Medicaid programs regarding how the requirement for 'brand medically necessary' in the prescriber's own handwriting can be accomplished through electronic prescribing. As this is a national issue, we suggest a change in federal law regarding certification in a prescriber's own handwriting or at a minimum development of a standard for electronic prescribing consistent with state mandatory generic programs/laws and federal laws to meet the intent of the 'brand medically necessary' requirement.

New York State would like to participate in the pilot testing of e-prescribing that will take place during the 2006 calendar year. As part of its efforts to reduce fraudulent prescribing, New York State initiated an Official Prescription Program that prevents alteration of paper prescriptions. In conjunction with that effort, the State is encouraging prescribers to use e-prescribing to prevent theft of these Official prescriptions, and as a means to further reduce fraud.

NCVHS has not advanced to HHS any recommendations for standards pertaining to exchange of medication history and medical history for the e-prescribing program. New York State recommends the use of existing systems where they exist.

HHS is considering use of the NPI for Medicare Part D e-prescribing transactions, and is looking for alternatives to NPI, especially in the short term. New York State supports the use of the NPI, as well as use of State issued professional licenses and Provider Identifiers, to identify e-prescribers.

Thank you for the opportunity to comment.

**Issues**

Background

The NYS Medicaid program is generally supportive of the proposed electronic prescribing rules provided that appropriate, flexible standards and patient safeguards are developed. This proposed rule may have a sweeping impact on all third party payers and result in standards adopted by all third party payers.

Background

Current E-Prescribing Environment

While NYS recognizes that electronic prescribing may speed prescription processing, we are concerned about potential steering of recipients to specific pharmacies, as well as directing prescribers to specific drugs. This is especially a concern when pharmaceutical manufacturers 'donate' hand held prescribing devices, software or hardware to prescribers or institutions. In order to prevent steering and safeguard a patient's freedom of choice, CMS must develop patient safeguards.

Electronic Prescription Drug Program

Critical messaging for formulary and benefit information must include, at a minimum, standardized third party billing information and patient/physician options for coverage of non-formulary drugs.

In relation to Medicare Part D and any potential wrap-around coverage provided by Medicaid programs for their dual-eligible population, it is imperative that foundation standards provide standard specific messages to pharmacies emphasizing that Medicare is the primary payer, especially when a secondary payer is billed as primary (i.e., Other Insurance--Bill Medicare first). A patient's insurance coverage listing the primary and secondary payers should be available to prescribers through the electronic exchange of information between the sponsor and prescriber. This would aid a prescriber in selecting an appropriate covered drug under the primary payer's formulary.

In addition to aiding the prescriber in selection of covered drugs under Medicare Part D or any primary payer, if a necessary drug is non-formulary, the pharmacy/physician messaging must include a message that the plan sponsor's exception process may be accessed.

**Submitter :** **Mrs. Elise Smith** **Date: 04/05/2005**

**Organization :** **American Health Care Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

Comments on Medicare Program; E-Prescribing and the Prescription Drug program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P

CMS-0011-P-33-Attach-1.PDF

202-898-2828
hdaub@ahca.org

April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-0011-P

***Re: Comments On Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P***

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule *Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P.* AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical LTC. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L.108-173, signed into law on December 8, 2004, took a giant step forward in providing increased benefits to Medicare beneficiaries in the critical area of prescription drugs. The legislation established a new voluntary prescription drug benefit under a new Part D of the Medicare program which is to be effective January 1, 2006. The new Medicare Part D will provide many benefits and also many challenges.

AHCA was pleased to submit comments on the proposed Part D rule implementing the MMA,[1] particularly in areas directly affecting LTC residents and LTC facilities.[2] We were gratified at CMS' responsiveness to our concerns in the Part D final rule[3] and in the guidance that CMS issued on March 12 regarding performance and service criteria for network LTC pharmacies (NLTCPS) and requirements for Part D Plan sponsors for a process for coverage transitions. There is still work to be done and many issues to be addressed, but we believe that CMS has made great progress. We value being part of the mutual effort of the government and the private sector to help Part D achieve its full potential of achieving better lives for our citizens, and in particular the lives of residents in LTC, and in continuing to improve the quality of their care.

The MMA also required that prescriptions and certain other information for covered drugs that are transmitted electronically must comply with final uniform standards promulgated no later than 2008 by the Secretary. These standards must meet MMA's requirements, as well as be compatible with other standards, including standards adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In the final Part D rule published on January 28, 2005, CMS requires Medicare Part D Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006. On February 4, 2005, CMS published the proposed rule providing the first set of uniform final standards for electronic prescribing (e-prescribing) under Part D for which we are now providing comments.

***The Importance of E-Prescribing in the LTC Environment***

The use of the standards is mandatory solely for Part D sponsors and even then only to receive or reply to e-prescribing transactions initiated by other entities. Providers that prescribe or dispense Part D drugs are required to comply with the standards only when they electronically transmit prescription information or certain other related information.

CMS indicates that while 75 percent of the 57, 208 pharmacies in the United States already have e-prescribing capability, only between 5 and 18 percent of physicians and other clinicians are e-prescribing. Except for certain exceptional initiatives,

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[1] *Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule, 69* Federal Register *46632,* August 3, 2004.

[2] We use the term LTC facilities to refer to nursing facilities and intermediate care facilities for the mentally retarded (ICFs/MR). CMS expanded the definition of the term "long term care" facilities in 42 CFR 423.100 of the Part D final rule to encompass ICFs/MR.

[3] *Medicare Program; Medicare Prescription Drug Benefit, Final Rule*, 70 Federal Register 4193, January 28, 2005.

AHCA assumes that few if any physicians are e-prescribing with respect to residents of LTC facilities. This picture must change. The benefits of e-prescribing for patients are enormous. CMS articulates just some of the potential benefits as follows:

- E-prescribing can help prevent medication errors because, at the time of prescribing, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication.
- E-prescribing can also improve quality, efficiency, and reduce costs, by:
    - Improving patient safety and quality of care through immediate access to medication history information, and the prevention of adverse drug events;
    - Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
    - Speeding up the process of renewing medications; and
    - Providing instant connectivity between the health care provider, the LTC pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.
- E-prescribing also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, CMS also believes that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management (which is designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions) will be enhanced by e-prescribing.

CMS believes that these improvements, enabled by e-prescribing programs, will occur through, among other things, improved prescription drug-related quality and disease management efforts, and ongoing improvements in information systems used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. CMS also believes that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented.

It is clear that all these benefits and enhancements to quality of pharmacy care, deriving in great part from advancements such as e-prescribing, must be provided to LTC residents as well as Part D beneficiaries who do not reside in LTC facilities. They will constitute an advancement in -- and become a fundamental and integral

part of -- the quality of care in LTC facilities. Nationally, there are 1.6 million nursing home residents; this is a major group taking multiple medications and each medication requiring multiple nurse/physician communications (phone and fax) on a regular basis.

The benefits of e-prescribing that CMS articulates could assist LTC facility compliance with Medicare and Medicaid requirements of participation. For example, the survey guidance for requirements governing medication errors and unnecessary drugs is currently undergoing major revision under CMS contract to the American Institutes for Research (AIR). The AIR product is intended to provide specific information to assist surveyors in making appropriate determinations and severity assessment of noncompliance cited under the related regulations. It is inconsistent for CMS on the one hand to "beef up" the survey guidance in this area, while on the other hand ignoring e-prescribing as a tool that could assist nursing facilities to achieve and sustain compliance.

Yet, CMS' proposed rule is completely silent on the impact of the e-prescribing standards in the LTC setting and thus utterly devoid of any recognition of the importance of e-prescribing to the LTC environment. In fact, the proposed foundation standards would not accommodate the LTC pharmacy services model because the standards are based on direct communication between the prescriber and the retail pharmacy and do not recognize the third critical entity involved in providing drugs in the LTC setting -- the LTC provider. Likewise, CMS has also failed to provide any consideration of how e-prescribing standards might require modification and further development to meet the complex operational and regulatory environment of LTC facility pharmacy services and the role of the consultant pharmacist, or addressed how the development and adoption of LTC e-prescribing could be supported and incentivized. Thus, CMS has not raised the issue of protection for LTC providers under the Anti-kickback statue related to certain e-prescribing incentives -- protection which the Office of Inspector General (OIG) intends to afford other providers, such as physicians, in further regulation.

It is also clear that if CMS hopes to substantively increase the participation of physicians in e-prescribing for Medicare patients, it cannot ignore the LTC patient population. Failure to address the LTC environment in the development of e-prescribing can have serious adverse consequences: it could disincentivize and impede physicians who have LTC patients from adopting e-prescribing technology and or it could disincentivize physicians from caring for LTC patients, thus exacerbating a bias that exists today. Without concurrently including LTC in physician e-prescribing efforts, chemotherapeutic care for the chronically ill will continue to be delivered in a silo, devoid of all benefits from instant information exchange, leaving the physician to deal with e-prescribing for one set of patients and continued use of phone and fax for others. Having physicians using multiple medication systems is confusing, burdensome, costly and will lead to error. This

situation, alone, has the propensity to derail physician e-prescribing technology efforts.

In the final e-prescribing rule and in its future activities in this area, CMS must rectify the omission of consideration of LTC and LTC residents. To that end, we recommend below several steps that CMS should take.

***Development of Standards for the LTC Facility Environment***

First, we ask that CMS work with the National Council for Prescription Drug Programs (NCPDP) on standards that will make possible and promote e-prescribing in the LTC environment. CMS has adopted the prescription SCRIPT standard of the NCPDP and certain NCPDP standards for eligibility. These final standards are referred to as foundation standards by CMS because they would be the first final set of final standards adopted for an electronic prescribing program. According to CMS adequate industry experience exists with respect to these proposed standards thus allowing CMS to propose and adopt these foundation standards as final standards without pilot testing. However, these standards, based on direct communication between the prescriber and the retail pharmacy, do not accommodate the LTC pharmacy services model. NCPDP has developed a work group to address e-prescribing in the LTC environment. We ask that CMS work with the group developed by the NCPDP to provide design alternatives for standards used within the LTC setting. We understand that the design alternatives being examined by the work group are focused on accounting for and connecting all three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility.

In order to ensure that futher e-prescribing standards work within the context of the three-way prescriber, LTC provider, LTC pharmacy environment, AHCA recommends that additional standards, as well as updates and revisions to e-prescribing standards be subject to formal agency rulemaking. E-prescribing standards represent substantive responsibilities for LTC providers, prescribers, and LTC pharmacies, and a Notice of Proposed Rulemaking (NPRM) process is the only way LTC providers can be assured of notice and an opportunity to comment on e-prescribing standards that affect the services provided to nursing home residents.

As CMS knows, the LTC facility bears the primary responsibility for safe and effective drug distribution to its residents. For example, the requirements with respect to nursing facilities are manifold and strict, as they should be. The core mandate is that "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care." 42 CFR 483.25. Further, "A drug whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort

or endangers his or her health and safety, then this requirement is not met." 42 CFR 383.60 and 483.75(h). In addition, as a vital part of the quality of care requirements, the facility must ensure that it is free of medication error rates of 5 percent or greater; and residents are free of any significant medication errors. 42 CFR 483.25 (m).

As indicated above, these regulatory mandates place the ultimate responsibility for safe and effective drug distribution with the LTC facility. A critical aspect of this responsibility is the fact that the medical record of the patient is kept at the LTC facility. Thus, a key operative concept in designing an operative LTC e-prescribing system is to acknowledge the responsibilities of the LTC facility, the role of the LTC facility as the guardian of the resident's medical record, and the key role of LTC facility staff.

The act of prescribing in the LTC facility environment involves direct communication between LTC nursing staff and the physician and further communication between the LTC facility staff and the LTC pharmacy. No matter how streamlined the process may become, the LTC facility stands at the heart of the process. Again, this is a model that involves three entities: the physician, the pharmacy, and the LTC facility. Any e-prescribing system that provides the benefits of e-prescribing to LTC residents must involve all three entities.

Most importantly, the system must facilitate and support the ability of the LTC facility to provide the highest quality of care for its residents and meet all of the mandates of law and regulation pertaining to the provision of pharmacy services. Thus, to reiterate, we ask that CMS work with the NCPDP designated workgroup to provide design alternatives for standards used within the LTC profession which will address the vital roles of the three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility. As CMS moves toward full implementation of electronic prescribing for medications covered under Medicare Part D, it is essential that the proper framework be developed for prescribing medications for LTC residents.

***Pilot Testing and Demonstrations***

Secondly, the MMA requires pilot testing for initial standards for which adequate industry experience is lacking. Testing of such standards would, pursuant to the proposed rule, occur during the 2006 calendar year. The results of the pilot project would be evaluated and, based upon those results, final standards will be published not later than April 1, 2008. The proposed rule indicates that in order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary is mandated to conduct an evaluation of the pilot project,

and to submit a report to the Congress on the evaluation, not later than April 1, 2007. Again, there is no inclusion of LTC providers.

We reiterate our request that CMS work with the NCPDP to develop and pilot test standards that are appropriate for the LTC environment. We are concerned that any pilot study will not provide a true picture of standardization needs for electronic prescribing unless the pilots include the full spectrum of health care, including long-term care. AHCA also recommends that the evaluation of the pilot testing specifically address the experience of physicians, LTC providers, and LTC pharmacies in its report to Congress on the outcome of the pilot testing.

Lastly, we ask that CMS use its demonstration authority to develop and test various appropriate e-prescribing models in LTC facility environments.

***Overcoming Barriers to E-Prescribing***

Third, CMS must help LTC overcome barriers to the development and application of LTC e-prescribing. In the proposed rule, CMS clearly recognizes the barriers to increased usage of e-prescribing by physicians. One major barrier is the cost of buying and installing a system which includes the time involved in training staff and changing record systems from paper to electronic. CMS also cites lack of reimbursement for e-prescribing costs and resources. Since CMS does not address the LTC environment, the agency never discusses the fact that such costs also will be borne by both LTC facilities and LTC pharmacies in evolving toward e-prescribing.

CMS should first assist the LTC profession in trying to estimate and quantify these costs and then work with LTC providers and pharmacies to find ways to assist the funding of this new technology. For example, with regard to physicians, CMS acknowledges that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees. CMS states that the OIG will create an exception to the Stark law and an Antikickback safe harbor for such e-prescribing physician incentives. If health plans consider similarly incentivizing LTC pharmacies and facilities to join physicians in the three-way LTC e-prescribing environment, then CMS and the OIG should consider similar legal protection for LTC facilities and pharmacies.

Lastly, as we have indicated above, a concomitant barrier to overall adoption of e-prescribing is prolonging an environment in which physicians would face having to use multiple prescribing systems: with e-prescribing for one set of patients and continued use of phone and fax for others. Thus assisting the LTC profession to meet the costs of participating in e-prescribing will help to hasten the adoption of this critical system by all physicians.

***CMS Support for LTC Profession Efforts in Information Technology, Adoption of Electronic Records and E-prescribing***

Last but not least, e-prescribing is only one facet of the overall revolution that is occurring in the development and adoption of health information technology and the development of electronic health records (EHRs). AHCA is at the forefront of an intensive comprehensive effort to support the development of electronic records and their adoption by LTC providers and the development of appropriate and necessary health information technology (HIT) for introduction to, and adoption by, LTC providers. We are on record with many efforts in these areas.

CMS itself acknowledges that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive EHR system with decision support functionality and that it must be interoperable with other functions of an EHR. CMS indicates that the need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. CMS acknowledges that one option might have been to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time.

However, CMS rejected this approach since it would postpone the implementation of any e-prescribing functionality, including the attendant benefits and was beyond the scope of the MMA. Instead CMS is attempting to propose foundation standards that are appropriately accredited and have adequate industry experience. CMS believes that this will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. CMS solicits comment on this approach, as well as on other critical success factors for assuring interoperability.

We agree with this approach since it is our belief that movement forward must be made on all these fronts -- but not without LTC -- and not without the support of CMS as AHCA proceeds with its many initiatives. For instance, we are identifying, reviewing, synthesizing and distributing existing steps/protocol for selecting software, systems and vendors; identifying the need for additional or enhanced criteria to improve the selection protocols; organizing an LTC summit bringing together LTC operators, vendors, and government officials; identifying products available and trying to resolve impediments to product development; collaborating on the Continuity of Care Record (CCR) as part of our EHR initiative; reviewing and commenting on HL7 EHR standards; and promoting LTC profession's efforts to align with Regional Health Information Organizations (RHIOs). This includes monitoring barriers preventing LTC from participating and helping AHCA affiliated state associations efforts to promote LTC partnerships with RHIOs.

***Conclusion***

In conclusion, LTC residents deserve the finest quality care possible. LTC providers have made enormous strides in improving and enhancing that care. They cannot be left behind as technological innovation is increasingly introduced into the health care environment. The LTC profession assisted by AHCA is taking giant steps in promoting the development of and access to quality enhancing technology.

In the final rule, CMS should address e-prescribing standards that would apply to the provision of pharmacy services in the LTC profession. Further it should articulate the ways and means that it would employ to promote and support e-prescribing in the LTC facility environment. This may include pilot testing, demonstrations and encouragement of health plan support for incentivizing LTC facilities and pharmacies to participate in e-prescribing. I would gladly work with you on these issues and welcome discussion with you on inclusion of the LTC in CMS' e-prescribing efforts.

Sincerely,

Hal Daub
President and CEO

**Submitter :** **Ms. Kristin Lewis** **Date: 04/05/2005**

**Organization :** **Tufts Associated Health Maintenance Organization**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Because of the need to ensure data security and privacy, we feel that health plans should be allowed to use their discretion in selecting E-Prescribing Point of Care Vendors. It takes considerable time and effort to validate appropriate security and privacy practices on the Point of Care Vendor side. While we agree that at least one Point of Care Vendor should be required, additional vendors should be at the health plan?s discretion and not required.

**Issues**

Regulatory Impact Analysis

Health Plans? Costs and Financial Benefits. CMS states that it believes that costs incurred by health plans will be minimal, even in those few cases where plans do not currently support e-prescribing directly or through PBM contracts. However, CMS further states that it is possible that some plans will experience consequential costs that CMS has not foreseen. CMS requests comments on possible costs to plans, and on steps CMS could take to ameliorate any unnecessary costs. CMS also requests comment on the Agency?s expectation that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans.

**Submitter :** **Phillip Rothermich** **Date: 04/05/2005**

**Organization :** **Express Scripts, Inc.**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-35-Attach-1.DOC

April 5, 2005

The Honorable Mark McClellan, M.D.
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

RE: File code CMS-0011-P

Dear Dr. McClellan:

Express Scripts appreciates the opportunity to comment on the NPRM for the Medicare Program; E-Prescribing and the Prescription Drug Program (CMS-0011-P) that was published in the Federal Register on February 4, 2005 (the "NPRM").

Express Scripts is one of the largest pharmacy benefit management (PBM) companies in North America, serving thousands of client groups including managed care organizations, insurance carriers, third-party administrators, employers, government and union-sponsored organizations. We currently provide pharmacy benefit services to six million seniors enrolled in a variety of funded retiree health plan arrangements.

Our company strongly supports the development of standards for electronic prescribing, and we have actively participated in the process of the National Committee for Vital Health Statistics leading up to the NPRM. We believe standards cannot be effective in encouraging adoption of electronic prescribing technologies or meaningfully impacting the deliver of quality, cost-effective health care, unless such standards are true *standards,* impacting *all* electronic prescriptions. We have worked on a bipartisan basis with both the Administration and Congress during the legislative process leading up to passage of the Medicare prescription drug bill, and we believe the Congress intended to achieve true standardization of electronic prescribing for the benefit of the nation's health care. We address this and other concerns in our comments.

Attached please find our comments (Attachment 1) on the NPRM. We thank you for the opportunity to comment on these proposed rules and regulations.

Sincerely,

EXPRESS SCRIPTS, INC.
By: Thomas M. Boudreau
Senior Vice-President and General Counsel

## ATTACHMENT 1

**Comment: I. BACKGROUND, A. Statutory Basis and II. PROVISIONS of the Proposed Regulation, B. Proposed Definitions**

According to the NPRM, "Electronic media" means:

*(1) Electronic storage media, including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or*
*(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission."*

This rule seems to include (but does not specifically mention) **electronic faxes**, since those transmissions were created in an electronic format, then transmitted electronically. Since electronic faxes are electronic media, they are also considered electronic prescriptions, per the definition on page 6273 of the NPRM (section 423.159):

*E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network.*

Electronic faxes cannot comply with the proposed standards, as they do not utilize the NCPDP Script standard. In addition, electronic faxes present special authentication concerns and will require special consideration, perhaps even specific standards. While the proposed definitions adequately capture what is electronic media and what is included in "e-prescribing," it will be important in the final rule to make special consideration for electronic faxing. Electronic prescribing generally will benefit from the elimination of electronic faxing as a means of transmission. However, until the industry is ready to support broad use of electronic data interchange ("EDI") transmission of prescriptions, electronic faxing will continue and will need to be specifically dealt with in the standards. In any case, we want to ensure that dispensers are not required to distinguish between traditional (paper) faxes and electronic faxes. It is difficult or impossible to distinguish between them.

**Comment: I. BACKGROUND, A. Statutory Basis and F. Evolution and Implementation of an Electronic Prescription Drug Program**

**Also relates to: II. PROVISIONS of the Proposed Regulation**

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American National Standards Institute (ANSI) accredited. We are concerned that in some cases this may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

While we support the goal of leveraging the capabilities, experience, and broad industry participation of ANSI-accredited organizations in the quest for identifying standards, we are concerned about including ANSI accreditation as a threshold for a standard to be considered to have adequate industry experience, given that the process by which these organizations work to develop standards is but one way to assess industry consensus. The Secretary, in reliance on NCVHS and the testimony it heard, is also capable of determining whether a sufficient industry consensus exists, and whether a particular transaction standard has been accepted and implemented broadly enough for purposes of determining whether adequate industry experience exists with the use of the transaction and whether that transaction standard should be adopted as a "standard" for purposes of the directive in the MMA.

Relying on industry standard setting organization creates a risk that parties with particular agendas or ulterior motives can "hijack" the process, preventing any standard from getting passed, despite broad consensus and/or the lack of any alternative standard for a given transaction type. Deferring these decisions to ANSI-accredited organizations, at least in cases where significant adoption and use of a standard exists, is an unnecessary additional step in the process, and is inconsistent with the directive in the MMA for the Secretary to adopt standards.

**Comment: I. BACKGROUND, A. Statutory Basis and H. Summary of Status of Standards for an Electronic Prescription Drug Program**
**(Also relates to I. BACKGROUND, C. Standards Design Criteria and IV. Regulatory IMPACT ANALYSIS)**

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Moreover, it could undermine the momentum that electronic

prescribing enjoyed even before Congress sought to promote it as a means to manage costs associated with the Part D benefit under the MMA. Without adoption by physicians, the benefits of electronic prescribing cannot be realized. Clearly this was not Congress' intent.

Specifically, we believe the preemption provisions adopted by Congress in Section 1860D-4(e)(5)(B) must be reasonably interpreted to address any state law or regulation that in any way relates (i.e., "pertains") to the electronic transmission of medication history, eligibility, benefits or the actual prescription for any drug designated as a "covered Part D drug." As discussed in more detail below, rules of statutory construction support this interpretation. This would create a single, predictable, national methodology for the electronic transmission of this type of information, whether within a state or across state lines, while respecting the ability of states to continue to regulate paper prescriptions which, by definition, are not transmitted across state lines.

This outcome does not require resort to interpreting the statutory language of "and" to mean "or," nor does it render paragraph (B) meaningless, but it does give meaning and purpose to the standards which the Act anticipates. The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer. "Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available.

CMS stated in the preamble to the NPRM that "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of state law that will require detailed analysis in all 50 states to figure out how existing state law should be read to mingle with federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a state requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that state require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payor?
- Does a Medicare prescription transmitted electronically need to meet state rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable state forbids such intermediaries?

- Can the physician or pharmacist be disciplined under state law where a prescription is sent electronically according to the federal rule but it is deficient for state law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payor) which can only be applied when the claim is adjudicated?

Uncertainty among physician and pharmacists about their professional obligations will diminish their willingness to adopt and use this technology. The likely result of all this confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. Consequently, we believe the statements (on page 6268 under Regulatory Impact Analysis) that suggest that the proposed standards will accelerate adoption of e-prescribing are misguided. The opposite, in fact, is true.

The Regulatory Impact Analysis, on page 6269, also states, in part:

> The primary method [to encourage adoption] chosen by the Congress was to increase the value of e-prescribing systems by mandating uniform standards for e-prescribing. Uniform standards reduce barriers to adoption by reducing uncertainty in the marketplace regarding which standards will be the industry standards of the future. These incentives are created without imposing substantial costs. For potential new e-prescribers, whose choice to adopt e-prescribing is voluntary, these standards provide the advantages of uniformity and reduced uncertainty, and, hence, reduce costs or increase benefits of adoption.

These statements are all in fact quite true to the extent that CMS is willing to create uniform "standards" as required by Congress under the MMA. However, the limited scope of what is proposed in the NPRM, coupled with the narrow view espoused regarding preemption, eliminate the possibility of achieving these benefits. Therefore, these statements are also misguided as applied to what is currently proposed.

By taking a partial approach and not creating a single, national standard that deals with all issues relating to electronic transmission of prescriptions, we believe the proposed rules do more to harm the progress of electronic prescribing than they do to advance adoption. The current 50-state scheme is difficult to navigate. Adding a 51st scheme that is to be interwoven into each of the other 50 does not solve the problem, but only creates an additional, and more burdensome problem. This certainly seems to conflict with the statutory requirement in Section 1860D-4(e)(3)(C)(i) which specifies that the design criteria for electronic prescription drug program standards require that the "standards be designed so that, to the extent practicable, they **do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists**." (emphasis added)

We believe that, in including the electronic prescribing program under the Act, and providing for standards which were to preempt state law, Congress intended to achieve a single national methodology for all electronic prescriptions, recognizing that some would ultimately be covered by the Medicare program. Stopping short of this in the name of federalism, and creating a confusing overlay that must be interpreted on a state-by-state

basis, undermines Congress' intent and benefits neither the federal government nor the states. It also undermines the goal of better, more cost-effective health care. This is clearly a problem of national significance where a single national approach is vital, and there is statutory authority enabling CMS to act.

The NPRM takes language from Section 1860D-4(e)(1), which relates to when prescribers are **required** to send prescriptions according to the standards, and inappropriately applies that language as a limitation on when the standards are applicable vis-à-vis state law, thus ignoring a distinct difference in that Section as opposed to the language in the preemption Section (1860D-4(e)(5)). Section 1860D-4(e)(1) states, in relevant part:

> [As of the applicable effective date], prescriptions and other information described in paragraph (2)(A) [describing the electronic prescription drug program under the MMA] for covered Part D drugs prescribed for part D eligible individuals that are transmitted electronically **shall be transmitted only in accordance with such standards** under an electronic prescription drug program that meets the requirements of paragraph (2). (emphasis added)

While the MMA did not mandate the use of electronic prescribing technologies, this first paragraph sets forth the intent that *if* such technologies are used in the treatment of a Part D eligible individual, then the established standards must be followed. Conversely, Section 1860D-4(e)(5) seeks to prevent states from deterring adoption by the imposition of conflicting or competing requirements related to electronic prescribing. It states:

> The standards promulgated under this subsection shall **supersede any State law or regulation that** -
>
> (A) is **contrary to the standards** or restricts the ability to carry out this part; and
> (B) **pertains to the electronic transmission** of medication history and **of information** on eligibility, benefits, and prescriptions **with respect to covered part D drugs** under this part. (emphasis added)

Assuming, as rules of statutory construction require, that the differences in these two sections were intentional, and putting them in the context of Congress' desire to promote uniformity and encourage adoption, we believe the statement at page 6257 in the NPRM that "… the best reading of [1860-D-4(e)(1)], as well as the intent of Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans…" is unfounded. To the contrary, we believe the statutory language makes clear Congress' intent for the Secretary to create a regulatory scheme to govern all electronic prescription of any drugs included in the Part D program, so as to ensure a single, national electronic prescription drug program that would be adopted and used consistently by prescribers to the benefit of Medicare and the rest of the health care system.

We believe a single, national set of standards for electronic prescribing are in the interest of all parties, including the states. The principal concern of states would not likely be that the federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that state boards of pharmacy typically seek to address in their rules. We believe the issues fall into four primary categories:

- transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- rules relating to formatting of prescriptions and documentation of the prescriber's intent
- rules relating to authentication of the prescriber
- rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of standards applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a patchwork of varying and sometimes conflicting federal and state laws affecting all electronic prescriptions. The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant state law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as federal standards are adopted for electronic prescriptions, they preempt any contrary state standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all state rules on those topics with respect to all electronic prescriptions. However, it will be imperative for the Secretary to move quickly in order to avoid confusion which may be created by only dealing with part of the problem.

**Comment: I. BACKGROUND, F. Evolution and Implementation of an Electronic Prescription Drug Program, and H. Summary of Status of Standards for an Electronic Prescription Drug Program**

Express Scripts believes it is vitally important for HHS to adopt a process by which the standards for electronic prescribing can evolve in conjunction with the industry's evolution and in a manner that is more flexible and practical than what currently exists under HIPAA. We believe this process should leverage the expertise and industry participation of ANSI-accredited standards organizations, however, HHS should work with the standards organizations to ensure interoperability between standards and across versions of standards.

In this same vein, we encourage HHS to pursue a course to modify the existing HIPAA rules to provide for a more flexible and practical approach to evolving standards, consistent with what is adopted for electronic prescribing.

**Comment: I. BACKGROUND, G. Electronic Prescription Drug Program and H. Summary of Status of Standards for an Electronic Prescription Drug Program. Also relates to: II. PROVISIONS of the Proposed Regulation**

**ASC X12N 270/271**

We support the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers.

We understand that there is not much (if any) industry experience in using the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the dispenser to the payor. In addition, the E1 message is not designed to handle multiple coverage (COB) responses as it is only designed to handle verification of a patient's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not being used, we recommend that it be excluded from the final rule. At minimum, we recommend that this transaction be piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

**Provider and Dispenser Identifiers**

We believe that the timeline currently in place for the implementation of the NPI should not be altered as any change will not likely result in a feasible solution and may create unintended difficulties for the industry. However, we do believe that having a single system for the identification of providers is in the industry's best interests, and the long-term goal should be to use the same identifier for all transactions which require one.

In the meantime, we believe CMS should make use of identifiers that are currently available and in use, rather than try to implement something new that will be replaced when the NPI becomes available. The NCPDP Provider Identifier Number is currently widely used by the industry and should be adopted for electronic prescribing until NPI is fully in place. For prescribers, the identifier most commonly used by the electronic prescribing industry is the DEA registration number. While we understand that DEA does not support use of the DEA number for this purpose, we believe it is most practical to adopt it for electronic prescribing in the short-term, with the recognition that it will be replaced in the near-term with the NPI. Any other approach will create significant inefficiencies by forcing the industry to change processes and adapt to something new, only to have to make additional changes in the next 12-18 months to adapt to the implementation of the NPI (scheduled for May, 2007).

**Formulary and Medication History Standards**

We support adoption of the RxHub standards for communication of formulary and medication history information between health plans/PBMs and technology vendors/prescribers. We believe these should be adopted in the final rule as foundation standards. We do not believe it is necessary for these standards to be validated by an ANSI-accredited organization, given that the participants in the industry that are doing electronic prescribing have effectively adopted these as their standards for communication of this type of information, and that the industry has extensive experience in the use of these standards. The vast majority of electronic prescribing solution providers and each of the three largest PBMs (representing over 150 million lives) are using these transaction sets today and have been for several years.

We value the contribution NCPDP and other ANSI-accredited organizations have made and continue to make in developing consensus among various industry participants. However, given that these standards were developed through an industry consensus process, that they have been implemented and used extensively by the industry, and that no alternative standards exist, the Secretary should adopt these as standards under the authority granted in the MMA. There is no value to be gained in delaying the adoption of these standards. Furthermore, given that there is not an ANSI-accredited standards development organization comprised solely of the entities who will use these transaction sets (i.e., payors and electronic prescribing solution vendors), there is a risk that industry participants without a direct stake in the outcome, who may prefer to slow down the adoption of electronic prescribing or otherwise influence it for their own gain, could derail accreditation of these standards without ensuring that an alternative that addresses the problem is approved, particularly since there are no other viable alternatives in existence.

**Comment: IV. Regulatory Impact Analysis, B. Impact on Health Plans/PBMs and C. Impact on Prescribers**

We agree with many of the statements in the NPRM regarding the potential benefits of electronic prescribing, both in terms of quality of care and of cost savings to many of the participants in the chain. However, we believe the NPRM fails to recognize the true costs of implementing the technologies necessary to provide formulary and benefit information at the point of prescribing and is incorrect in it's assessment that there will not be any material impact to any participant in the chain. Cost or, perhaps more accurately, a lack of documented cost/benefit analysis, has been one of the primary barriers to adoption thus far. Furthermore, there are costs involved in supporting electronic prescribing that the industry may not be prepared to absorb, transaction fees in particular.

It is important to distinguish the transaction costs associated with conducting electronic prescribing from the costs associated with supporting electronic prescribing functionality according to the standards to be adopted. While some of the larger PBMs have implemented electronic prescribing capabilities and have historically supported the transaction fees associated with providing formulary and benefit information for electronic prescribing, it is not clear, particularly given how the PBM market is evolving, that payment of these fees by PBMs can or will continue, and there is a lack of precedent for other parties in the chain paying these fees directly. The market will have to sort out where the value from electronic prescribing accrues, and allocate fees accordingly. It will be important for the anticipated pilot tests to carefully measure where and to what extent value accrues from electronic prescribing, in order to better inform the market as to how these costs could be allocated.

One way to reduce the costs associated with providing electronic prescribing technologies to the market will be to implement a single, national set of standards for all electronic prescribing, so that technology vendors do not have to incur inordinate expense in researching and keeping up-to-date on the evolving federal and state regulatory schemes, and developing systems to comply in each jurisdiction in which they operate.

**Contact Information**

If you have any questions relating to our comments, please contact:

Phillip A. Rothermich
Vice President, Business Development
Express Scripts, Inc.
13900 Riverport Drive
Maryland Heights, MO 63043
(314) 702-7109
fax (314) 702-7657
prothermich@express-scripts.com

**Submitter :** **Ms. Laura Blum** **Date: 04/05/2005**

**Organization :** **JCAHO**

**Category :** **Private Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-0011-P-36-Attach-1.DOC


April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-1850
http://www.cms.hhs.gov/regulations/ecomments

RE: Comments on Medicare Program: E-Prescribing and the Prescription Drug Program

File Code: CMS-0011-P

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) appreciates the opportunity to comment on the proposed rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). The Joint Commission is the nation's oldest and largest standard-setting and accrediting body in health care.

The Joint Commission evaluates and accredits more than 15,000 health care organizations and programs in the United States. Our accreditation programs evaluate the performance of home care agencies; ambulatory care settings whose services range from primary care to outpatient surgery; behavioral health care programs; nursing homes; hospices; assisted living residencies; clinical laboratories; and managed care plans. Further, the Joint Commission is active internationally and has provided consultation and accreditation services in over 60 countries.

This rule proposes to adopt uniform standards for electronic prescribing that promote patient safety, quality of care, as well as cost savings for the new Prescription Drug Program (PDP)—known as Medicare Part D. This proposed rule describes the NCVHS process and recommendations as well as the process to implement the standards using an incremental approach. Ultimately, the goal is to achieve an electronic health record system and this proposed rule on electronic prescribing is a step in the right direction. Until health care reaches its goal of interoperability, studies estimate that broad implementation of electronic prescribing will prevent adverse events, improve care (e.g. greater continuity of care) and reduce costs.

It is evident that in the course of drafting the proposed rule, CMS and NCVHS staff had to address a myriad of issues associated with electronic prescribing in a complex environment. We recognize the tremendous amount of work that has gone into the preparation of this proposed rule and commend CMS and NCVHS on a job well done. JCAHO staff attended several NCVHS hearing on electronic prescribing and witnessed the extensive information gathering process that was undertaken prior to drafting this proposed rule. Along with general comments, this letter addresses the following:

- Initial standards versus final standards
- Criteria to assess adequate industry experience
- State preemption
- Regulatory impact to improve patient safety and quality
- Incremental approach for adoption and implementation

General Comments

To promote patient safety and quality care, the Joint Commission is a strong supporter of the development of a health care information technology infrastructure. The Joint Commission recognizes that electronic prescribing is an important stepping-stone for achieving interoperability. The Joint Commission can provide invaluable assistance in developing and promoting electronic prescribing standards. Our experience in developing standards and performance measurement metrics, and issuing National Patient

Safety Goals provides valuable insights that can facilitate the development and adoption of electronic prescribing.

*JCAHO National Patient Safety Goals*

The Joint Commission's National Patient Safety Goals are closely aligned with the goals that support the establishment of an electronic prescription program. For example, in an effort to reduce communication errors, the Joint Commission issued a Patient Safety Goal that requires a person receiving a verbal or telephone orders to verify the accuracy of the information by "reading back" the complete order or test results. A 2005 National Patient Safety Goal requires health care providers to accurately and completely reconcile medication use across the continuum of care. To achieve this goal, providers must develop a process for obtaining and documenting a complete list of patients' current medications upon admission. The process must include a comparison of the medications the organization provides with those on the patient's list. A complete list of the patient's medications must also be communicated to the next provider of service when a patient transfers to another setting, service, practitioner or level of care within or outside the organization.

Initial standards versus final standards

Section 1860D-4 (e) outlines the distinct provisions for initial and final standards. Given the obstacles of electronic prescribing related to the lack of interoperability and inadequate industry experience with many electronic prescription standards, it is prudent for HHS to pilot test disparate standards before issuing final standards by April 1, 2008. Additionally, it will take time to process applications from physicians, physician groups, hospitals, prescription drug plan sponsors, Medicare Advantage organizations and pharmacies who want to pilot new or emerging standards.

An issue for consideration is that the foundational standards will not be tested against each other. Hence, a better delineation of "testing" may be required for certain standards proposed in this regulation. While the Joint Commission supports CMS's accelerated timetable to roll out the foundational standards, we also recommend that CMS maintain the more conservative 2008 projection to accommodate unexpected debates.

Criteria to assess adequate industry experience

The proposed rule outlines criteria to assess adequate industry experience with those standards that already exist (i.e. standards that do not need to be pilot tested). The Joint Commission supports these criteria to assess adequate industry experience.

State Preemption

The proposed federal rule indicates that a state law cannot be contrary to the rule if the law pertains to electronic prescribing under Part D. State preemption is a critical and complex issue because many prescribers transmit across state lines. The language regarding state preemption in the proposed rule serves as a framework to states as they contemplate legislation regarding electronic transmission of prescriptions. This rule serves as a guideline because it allows a state to draft a law that suits its needs and budgetary capabilities as long as it is consistent with the federal rule.

Regulatory Impact to Improve Patient Safety

As noted in the proposed rule, electronic prescribing can improve quality, efficiency and reduce costs by providing real-time access to drug information and instant connectivity between health care providers. A primary objective of this proposed rule is to enhance patient safety. The proposed electronic prescribing standards cover: transmission of data about the patient's drug utilization history, possible interactions, and information on the drug plan (e.g., formulary and cost sharing, lower-cost, and therapeutically-appropriate alternatives). These are important pieces of information that should be accessible from any patient safety information system.

Incremental Approach

The MMA (Section 1860D-4(e)) requires the implementation of a pilot project unless there is adequate industry experience with whatever standards the Secretary is planning to adopt. This proposed rule puts forth a basic set of foundational standards- or building blocks- that are ready for implementation and recommends pilot testing more advanced standards that are less mature.

The Joint Commission supports phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, Medicare Advantage organizations, and PDPS to comply with the foundational standards. These standards could facilitate the transmission of medical history, alerts to adverse drug interactions, and suggestions for lower-cost, therapeutically equivalent alternative medications. The incremental approach is preferable over a "big-bang approach" in which the federal government mandates overnight compliance.

As part of the incremental approach, CMS proposes both mandatory and voluntary elements to encourage adoption of the standards. The Joint Commission agrees that the mandatory elements to encourage adoption are enabling and affirming for providers (e.g., positive financial incentives, increasing the value of e-prescribing systems, mandating uniform standards).

Once again, we commend CMS's hard work to adopt standards for electronic prescribing. The Joint Commission stands ready to work with CMS to share Joint Commission's expertise. If you have any question or require additional information regarding the issues presented in this letter, please contact Laura Blum, Associate Director of Federal Relations, at lblum@jcaho.org or 202.783.6655.

**Submitter :** **Ms. Lorraine Tarnove** **Date: 04/05/2005**

**Organization :** **American Medcial Directors Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-37-Attach-1.DOC

CMS-0011-P-37-Attach-2.DOC

*A national organization of long term care physicians committed to quality care*

**American Medical Directors Association**

**10480 Little Patuxent Parkway**
**Suite 760**
**Columbia, MD 21044**
410/740-9743

**Washington, DC**
301/596-5774

**Toll Free**
800/876-AMDA

**FAX**
410/740-4572

**www.amda.com**



April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert Humphrey Building
200 Independence Avenue S.W.
Washington, D.C. 20201

*Re: E-Prescribing and the Prescription Drug Program; 70 Fed. Reg. 6256 (Feb. 4, 2005); File Code CMS-0011-P*

Dear Administrator McClellan:

The American Medical Directors Association (AMDA) appreciates the opportunity to comment to the Centers for Medicare and Medicaid Services (CMS) on this important proposed regulation. AMDA represents more than 7,000 medical directors, attending physicians, and others who practice in nursing homes. AMDA physicians see an average of 100 nursing facility patients per month per member (approximately 8.5 million visits in 2000 or 42 percent of the total number of nursing facility visits that year). AMDA physicians also care for patients in other venues in the long term care continuum, which includes home health care, assisted living settings, hospice and other sites of care for the frail elderly. Our comments on this proposed regulation reflect that experience, as well as the commitment to provide the best quality of care to our patients.

Generally AMDA supports the use of electronic prescribing and electronic health records, although we are cautions regarding the level of impact the proposed regulation will have on long term care settings.

<u>Electronic Prescription Drug Program</u>
The prescribing environment in long term care settings raises additional issues regarding implementation of e-prescribing, because the nursing facility represents an additional “loop” in the prescription

process. In the vast majority of cased, physician orders are given directly to the nursing facility, which, in turn, sends them on to a long term care pharmacy. Leaving the nursing facility out of this loop will frustrate efforts to achieve e-prescribing for the 1.6 million residents of nursing facilities.

Anti-kickback Statute Safe Harbor and Stark Exception

The MMA (Section 1860-D-4(e)(6)) requires HHS to promulgate regulations that provide for a safe harbor under the anti-kickback statute and an exception under the physician self-referral statute for nonmonetary remuneration in the form of hardware, software or information technology and training cervices that are necessary for electronic prescribing. The statute specifies as subjects for safe harbors and exceptions:

- By hospitals, for members of their medical staffs;
- By group practices, for prescribing health care professionals who are members of the practice; and
- For MMA Part D drug plans, by drug plan sponsors for pharmacists and prescribing health care professionals.

The intent of this provision, to promote conversion to e-prescribing, addresses the ability of some large providers or groups of providers to assist the health care professionals with which they work. Unless specifically excluded by legislative language, we believe that CMS has the flexibility under this provision to allow safe harbors and exceptions for drug plans to also provide such nonmonetary remuneration to nursing facilities, as well as prescribing health care professionals who care for nursing facility residents.

Incentives for Implementing E-Prescribing

AMDA reiterates our concerns regarding the need for incentives for physicians and nursing facilities to adopt e-prescribing technology. The cost of hardware and software for e-prescribing is likely to be at least equaled by the attendant costs of training staff and reorganizing office and facility operations. As one of our physicians put it, “At this point, it seems cost-prohibitive to implement e-prescribing on the scale necessary to see the outcomes for which we strive.” Physicians and nursing facilities will arguably absorb much of the cost of adopting e-prescribing, not only in terms of hardware and software, but also in modifications that will be needed to train staff and reorganize operations. Yet many of the benefits touted for e-prescribing will occur “downstream” in the health care system.

For nursing facility patients, physician prescriptions are generated at the facility level, so that incentives to nursing facilities must be created in order to support the shift to e-prescribing in long term care.

We support incentive payments for physicians for e-prescribing under both managed care and independent drug plans. Few long term care patients are likely to be enrolled in MA-PDPs (managed care drug plans), so that restricting the ability for physician incentives to only MA-PDPs will not reach the vast majority of physicians who prescribe medications for long term care patients. Physician overhead is high, and current

reimbursement levels are not likely to encourage individual practitioners to invest in e-prescribing technologies.

CMA anticipated future pilot tests for e-prescribing, and AMDA suggests one that would focus on incentives for and impact of e-prescribing in long term care settings.

AMDA appreciates the opportunity to comment on these proposed regulations. Please feel free to call me if you have questions or wish additional information.

Sincerely,

Lorraine Tarnove
Executive Director

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April 5, 2005

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Sincerely,

Lorraine Tarnove
Executive Director

**Submitter :** **Date: 04/05/2005**

**Organization :** **Council for Affordable Quality Healthcare (CAQH)**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-38-Attach-1.DOC

CAQH COUNCIL FOR AFFORDABLE QUALITY HEALTHCARE
a catalyst for positive change

April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Centers for Medicare and Medicaid Services:

The Council for Affordable Quality Healthcare (CAQH) is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit Notice of Proposed Rule Making (NPRM) (42 CFR Part 423).

CAQH is a not-for-profit alliance of the nation's leading health plans and networks that develops, implements and promotes collaborative initiatives to help make healthcare more affordable, share knowledge to improve the quality of care, and make administration easier for physicians and their patients. Among the initiatives currently underway, CAQH has been at the forefront of efforts to promote e-prescribing and integrated access to a standardized, single source of formulary information from all payers.

In March 2004, CAQH partnered with RxHub to create a comprehensive, centralized source of formulary data. Formulary information from participating CAQH member health plans is being combined with that from RxHub's participating PBMs to create a centralized formulary file available to technology vendors. As a result, physicians have access to more accurate and complete information from a larger number of plans when reviewing treatment options with patients at the point of care. The combined database covers a majority of commercially insured Americans.

Because of our work with electronic formularies, our comments here focus mainly on that particular portion of the NPRM as well as our market experience with e-prescribing.

**BACKGROUND**

*"Section 1860D-4(e)(4)C)(ii) of the Act also permits an exception to the pilot testing for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users." (F.R. page 6257)*

CAQH supports adoption of the RxHub protocol for formulary by CMS and can confirm that there is reasonable industry experience with the standard. However, based on the experiences of our member plans with HIPAA implementation, CAQH recommends that the RxHub formulary standard be included in the 2006 pilot tests.

*Formulary and Medication History Standards. (F.R. page 6263)*
*"We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards."*

Our experience has shown that to gain provider adoption of formulary, e-prescribing tools need to include formulary data for at least 70% of a provider's payer base. Thus, HHS's consideration of the RxHub formulary protocol is supported by CAQH since, if adopted, it would increase the number of payers using the same data standard, which should increase provider interest in adopting e-prescribing.

In terms of the characteristics of the RxHub formulary standard, the data content of the standard that is currently under NCPDP consideration includes all of the information identified as critical. In addition, the RxHub standard allows for important flexibility in linking the correct formulary to the patient; in that, the standard allows for formularies at both the product (plan) level and at a patient-specific level.

Because the rate of e-prescribing varies widely by region, flexible methods to link patients to formularies will be needed for some time. Plans will then be able to make their own cost-benefit decisions on which method is most effective for their respective markets. While there is a need to eventually link all formularies to the individual patient, moving to such a system will be costly to some plans in the short-term and should be viewed as a longer-term, but desirable goal.

**IMPACT ANALYSIS**

*B. Impact on Health Plans/PBMs (F.R. page 6269)*
*"We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs. We also request comment on our expectation, discussed below, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. The only expenses attributable to health plans by this impact analysis are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing."*

From April 2003 to March 2004, CAQH conducted an e-prescribing pilot program in partnership with MedStar Health, Dr. First, and Safeway in the Washington D.C. area. 120 area physicians participated in the 12-month pilot and generated approximately 127,000 electronic prescriptions. Physicians were given the option of whether to enable the formulary check function and approximately 90 (75%) decided to do so. However, only 22% of enabled users actually referenced formulary. The key reasons for the low usage rate were:

- Time needed for manual entry (i.e., locating the patient's correct formulary and entering the drug name)
- Gaps in payer coverage (e.g., a large local plan did not participate)
- Time constraints/other priorities
- Lack of know-how
- Lack of interest

Although the number of enabled formulary participants was relatively small, the pilot program successfully demonstrated that prescribers will act on formulary warnings, and those actions can result in varying levels of savings for health plans and members (patients). Between the 1st and 4th quarters of the pilot, there was a 20% increase in providers changing a drug vs. ignoring or canceling it after receiving a non-formulary warning. One health plan that participated in the pilot noted a 35% net savings in health plan drug costs *when* a formulary warning was given, with an average savings of $29.21 per prescription for the initial prescription.[1] Other health plans, however, experienced minimal savings due to the low number of "hits" against the plan formulary. Members experienced savings in the form of reduced copays for on-formulary prescriptions.

In addition to these savings, health plans also incur direct costs internally. These costs are related to initial technology programming to meet the RxHub formulary standard (or other e-prescribing standards that may not be widely used) as well as staff costs for maintaining updated electronic formulary data and performing regular quality assurance checks on data files. As the e-prescribing market continues to evolve, health plans may also incur external charges for e-prescribing related transactions.

*C. Impact on Prescribers (F.R. page 6270)*

The Washington D.C. e-prescribing pilot program did result in reduced call volume between provider offices and pharmacies to resolve issues, and in time savings due to improved access to medication lists for provider office staff. Because of the small size of the pilot, however, providers were reluctant to quantify the savings amounts.

Clearly savings are possible for all stakeholders, but additional analysis is warranted.

CAQH appreciates the opportunity to provide these comments and is supportive of HHS's efforts to accelerate the adoption of e-prescribing. If you would like additional information on the results of our Washington D.C. pilot program, please do not hesitate to contact me.

Sincerely,

Robin J. Thomashauer

Robin J. Thomashauer
Executive Director

[1] Due to the small number of participants, these results cannot be extrapolated to all health plans.

**Submitter :** **Mr. Bruce Rodman** **Date: 04/05/2005**

**Organization :** **National Home Infusion Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-39-Attach-1.PDF

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
3. The submitter had intended to attach more than one, but not all attachments were received.
4. The type of document provided was a password-protected file. CMS was given read-only access to the document.

We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Mr. Thomas Leary** **Date: 04/05/2005**

**Organization :** **HIMSS**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-40-Attach-1.DOC

CMS-0011-P-40-Attach-2.DOC

230 E. Ohio Street, Suite 500
Chicago, IL 60611-3269

Tel 312 664 4467
Fax 312 664 6143

www.himss.org

April 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Dear Dr. McClellan:

On behalf of the 15,000 individual and 250 corporate members of the Healthcare Information and Management Systems Society (HIMSS), we are pleased to provide comment on the Medicare Program: E-Prescribing and the Prescription Drug Program (42 CFR Part 423). As the healthcare industry's only membership organization exclusively focused on providing leadership for the optimal use of healthcare information and management systems for the betterment of healthcare, HIMSS is uniquely qualified to provide comment on the proposed rule.

Overall, HIMSS applauds CMS for promulgating the proposed rule. E-Prescribing is one of the integral steps to achieving broad deployment of electronic health records (EHRs).

Our comments focus on the following three issues:

1. Most significantly, HIMSS is concerned that the Foundation Standards identified in the proposed rule may not be adequately tested. HIMSS recommends a pilot program to determine understanding and use of the foundation standard in real settings.

2. The National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to go with a legal entity versus a physical location or healthcare location enumeration. We would also like to emphasis that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that Integrating the Healthcare Enterprise (IHE) will continue to help drive the healthcare industry toward interoperability.

3. Finally, HIMSS is encouraged by the public discussion that CMS is considering exemptions for Anti Kickback Act and Stark Regulations for healthcare IT efforts between various entities. To reiterate our comments from the January 2005 Collaborative Response to the ONCHIT RFI, complete interoperability of healthcare must provided by any entity seeking a safe harbor. Establishing a

230 E. Ohio Street, Suite 500
Chicago, IL 60611-3269

Tel 312 664 4467
Fax 312 664 6143

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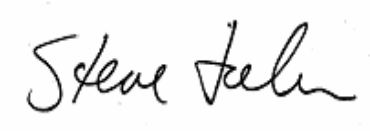
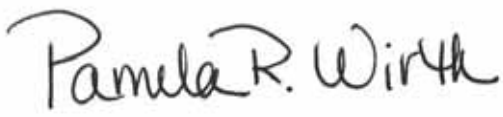
"Standards and Policy Entity" would provide the means of assessing the need for safe harbors as information sharing networks are created, especially in meeting the needs of rural and underserved communities. We encourage CMS to work closely with the Office of the National Coordinator to continue to move the process for the Standards and Policy Entity into an implementation phase of development.

We look forward to continuing our excellent working relationship with CMS, offering the collective voice of our membership as the proposed rule is finalized and collaboration underway. If you need any additional information, please contact Mr. Thomas M. Leary, HIMSS Director of Federal Affairs at tleary@himss.org or 703.299.9712.

Sincerely,





H. Stephen Lieber, CAE
HIMSS President/CEO
and

Pamela Wirth, CPHIMS, FHIMSS
Chair HIMSS Board of Directors

VP/CIO
Susquehanna Health System

**Healthcare Information and Management Systems Society**
**Comment on CMS-0011-P: on CMS Proposed Rule: Medicare Program;**
**E-Prescribing and the Prescription Drug Program**
**Submitted April 5, 2005**

# Background

The Centers for Medicare and Medicaid Services (CMS) rule proposes to adopt standards for an electronic prescription drug program (hereafter referred to as 'E-Prescribing') under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the Foundation Standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in an incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.

Section 1860D—4(e) of the Act specifies that initial standards, which are used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. Pilot testing is not required for those standards for which the Secretary of the Department of Health & Human Services (HHS), after consultation with affected standard setting organizations and industry users, determines there is "adequate industry experience." The Secretary is required to provide a report to the Congress by April 1, 2007.

Final standards may be adopted by the Secretary as a result of the pilot project. However, if the Secretary, after consultations, determines that pilot testing is not required because there is adequate industry experience with the standards, those standards may be adopted as final without pilot testing.

# Overview of HIMSS' Response

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM (Notice for Proposed Rule-Making). Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule.

Overall, HIMSS applauds CMS for promulgating the proposed rule. E-Prescribing is one of the integral steps to achieving broad deployment of electronic health records (EHRs). However, we have several concerns that require comment. Most significantly, HIMSS is concerned that the Foundation Standards identified in the proposed rule may not be adequately tested, and therefore recommends a pilot program to determine understanding and use of the Foundation Standards in real settings.

Additionally, we have concerns that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to go with a legal entity versus a physical location or healthcare location enumeration. We would also like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that Integrating the Healthcare Enterprise (IHE) will continue to help drive the healthcare industry toward interoperability.

Finally, HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for healthcare information technology (HIT) efforts between various entities. To reiterate our comments from the January 2005 Collaborative Response to the Office of the National Coordinator of Healthcare Information Technology (ONCHIT) Request for Information (RFI), complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing

a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information-sharing networks are created, especially in meeting the needs of rural and underserved communities. We encourage CMS to work closely with ONCHIT to continue to move the process for the Standards and Policy Entity into an implementation phase of development.

## Standards-Section 1860D-4(e)

**Summary of Proposed Rule**

Under the MMA, the HHS Secretary is given the authority to adopt proposed standards as final standards prior to the dates specified in the statute. Pilot testing is required only for standards that do not have prior adequate industry experience. Final standards are required by April 1, 2008.

## HIMSS' Response

**I. A.1: Initial Standards Versus Final Standards**

As the largest information systems organization representing healthcare providers and systems vendors, HIMSS respectively submits that there is not adequate industry experience with the standards proposed as "Foundations Standards." Additionally, the proposed Foundation Standards may not fully meet the criteria set out in Sections 1.F and 1.G. We strongly encourage CMS to utilize the pilot process for all E-Prescribing standards.

This recommendation is based on sound information systems principles, the lack of experience with the proposed Foundation Standards in the healthcare provider community, and concern that the proposed Foundation Standards have too many implementation options to achieve the desired E-Prescribing capabilities.

**System Testing of Standards**

Successful deployment of information systems requires testing of individual components or units, and testing of collections of units through full system testing. If one unit changes, regression testing is required to ensure that the total system still performs as designed. A thorough design, analysis and testing process should be conducted for the full set of standards through pilot testing.

E-Prescribing, as envisioned in the mandates of MMA, is a very complex system unlike any current implementation. The full collection of pertinent standards should be tested both as individual components and collectively as a complete system. Pilot testing is needed on the as-yet-undeveloped or unfinished standards (e.g., Formulary, Medication History, RxNorm or similar prescriber-level drug dictionary and the Sig standard).

**Lack of Healthcare Provider Experience with Proposed Standards**

While widely used in retail pharmacy and pharmacy benefits management, NCPDP standards have had very limited use in provider environments. Providers are, of course, a significant constituency that will be essential for the success of E-Prescribing. In the HIMSS/Phoenix Systems Winter 2005 survey of HIPAA compliance, we found that even two years after the mandated implementation date, only 73% of providers and 70% of payors are capable of handling HIPAA transactions including the 270/271. Compliance with the 270/271 was a mere 31% for providers and 33% for payors. We know that the percentage actually using the transactions routinely is substantially less than the percentage claiming capability. (See http://www.himss.org/Content/files/WinterSurvey2005.pdf for the full survey report.)

HIMSS considers this low level of utilization as evidence of a failure to meet the requirement for "adequate industry experience" for acceptance of any standard as a foundation standard.

**Proposed Standards Necessary But Not Sufficient**

The standards proposed by CMS as Foundation Standards can be used to meet E-Prescribing objectives. However, the standards allow so many options that a system may be perfectly compliant in the standard but not capable of supporting Part D E-Prescribing, let alone a "uniform means" of conducting E-Prescribing. The 270/271 illustrates this problem. This transaction pair has a number of levels. While a Level 1 implementation is HIPAA compliant, it is useless for E-Prescribing because the 271 response is a basic Yes/No. Part D E-Prescribing standards need a minimum of Level 3 of the 271 response, which will include benefit information (the "EB" record segment 2110) such as co-payment. Substantial study through pilot testing is needed to determine if the 270/271 can accommodate the total possible benefit/formulary structure a PDP or MA-PD may want to implement. While the 270/271 transaction may be capable of meeting the objectives of an E-Prescription, there are too many optional segments and fields in this standard for simply specifying ASC X12N 270/271. An MMA E-Prescribing Companion Guide, if not a separate standard, is necessary. Because E-Prescribing must support-tiered and other benefit structures related to formulary, the 270/271 Companion Guide must be prepared in the context of formulary communication standards and all other E-Prescribing standards. Please see our response in the Interoperability section (starting on line 370) regarding other best practices that could be used to ensure the proper profiling, testing and implementation of E-Prescribing standards.

The details that make the 270/271 inadequate reflect one of the major reasons HIPAA has failed to meet the promise of efficiency and savings. Realization of the benefits of Part D E-Prescribing as envisioned by the Legislature requires well planned and executed testing and piloting of the full set of standards. HIMSS stands ready to assist CMS in accomplishing this important task.

## State Preemption-Section 1860D-4(e) (5)

**Summary of Proposed Rule**

The standards promulgated under this subsection shall supersede any state law or regulation that is (A) contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

## HIMSS' Response

Clarification is needed regarding whether the state law preemption also applies to the prescription of controlled drugs. HIMSS believes that state law preemption should be very inclusive and incorporate controlled drugs, as well as any other state rules or laws that discourage or prevent electronic prescribing.

Testimony was previously given to the National Committee on Vital and Health Statistics (NCVHS) indicating that state variations would impede the development and implementation of E-Prescription systems by adding complexity to the HIT industry.

It has been HIMSS' position that E-Prescribing regulations, to every extent possible, should also be preemptive of state regulations regarding transaction standards and pertinent vocabularies. If preemption is not possible, CMS should prepare, distribute and support model state legislation and regulations to promote interstate consistency.

In addition, HIMSS recommends that these preemptions cover all electronic prescriptions including those covered by all other health plans, and not only Medicare Part D drug coverage as it is unreasonable to expect providers to use different rules for different patients.

## Anti-kickback Statute Safe Harbor and Stark Exception –

## Section 1860D-4(e) (6)

**Summary of Proposed Rule**

HHS' Office of the Inspector General will provide regulations for a "safe harbor" from sanctions and prohibition with respect to the provision of non-monetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. This applies in the case of hospitals to their members of medical staff; group practices, by the practice to prescribing healthcare professionals who are members of such practice; or a prescription drug plan (PDP) sponsor or MA organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing healthcare professionals.

## HIMSS' Response

Legal and policy changes (e.g., Stark Safe Harbor and Anti-kickback Safe Harbor) and financial incentives that increase the healthcare IT market should be structured to align the economic incentives of all stakeholders with the achievement of effective, practical interoperability. A significant barrier to achieving interoperability is the current challenge of building consensus among stakeholders, including healthcare providers, who have competing economic interests with respect to interoperability standards and policies, whether it pertains to E-Prescribing or other types of healthcare information exchange.

Significant legal and policy changes and financial incentives that encourage market expansion should be used to foster the deployment of true, practical interoperability standards once they have been established.

The present Stark law exemptions must be clarified. HIMSS recommends that safe harbor status for health information exchange be provided under a Standards and Policy Entity (SPE), as proposed in the Collaborative Response to the ONCHIT RFI, January 18, 2005. The SPE is a public-private collaborative entity that identifies and specifies the detailed implementation rules, including business rules, for the standards and policies that make up the common framework – which consists of the essential technical and policy standards necessary to ensure interoperability, serve the patients whose data it shares, and connect systems of varying technical sophistication. The SPE identifies and recommends the technical standards and information policies essential for establishing privacy, security and interoperability. The SPE is responsible for the identification, specification, interpretation, and dissemination of these standards and policies. E-Prescribing and related health information exchange standards should be governed by the SPE, who can determine if full interoperability is provided and recommend what safe harbors, if any, should be allowed. (See the Collaborative Response to RFI for the National Health Information Network (NHIN), lines 189-192 and 1048-1054, http://www.himss.org/ASP/ContentRedirector.asp?ContentID=64748.)

It is critical that such anti-kickback exemptions and safe harbors also be pre-emptive of any state regulations or rules that are more restrictive in order to promote E-Prescribing use.

## Electronic Prescription Drug Program

**Summary of Proposed Rule**

The Act specifies that an electronic prescription drug program for covered Part D drugs for part D enrolled individuals shall provide for the electronic transmittal to the prescribing healthcare professional and the dispensing pharmacy and pharmacist of the following:

- Prescription;
- Information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization);
- Information on the drug being prescribed or dispensed and other drugs listed on the medication history;
- Information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments; and
- Information that related to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed upon request of the professional or pharmacist involved.

## HIMSS' Response

**Formulary**

HIMSS believes that a controlled vocabulary for drugs correlated to National Drug Code (NDC) code will be essential to the success of the program. In the "Bar Code Label Requirements for Human Drug Products and Biological Products; Final Rule," as well as in the Proposed Rule, the Food & Drug Administration (FDA) committed to a separate rulemaking initiative to address the inadequacies and deficiencies of the NDC system (II.C.1) and to maintaining a database of all unique NDC numbers identifying dosage, strength, nature, and form of administration (VII.D and VII.E.6.). We are unaware of any movement on these critical issues. While the NDC system has apparently been acceptable for the pharmacy supply chain, E-Prescribing and point-of-care systems would require a much improved system for identifying medications at the time of prescribing. As our industry moves forward with not only bar code-enabled medication administration, but also initiatives such as computerized provider order entry (CPOE) or E-Prescribing, the deficiencies and limitations of the current NDC system become all too evident. From the provider perspective, there is a need for development of a standard "doctor-level" dictionary of medications. The NDC code standard addresses pharmacy packages. Even if there were no problems with the NDC code, it does not meet provider needs where different systems will use different vocabularies.

The government project, the National Library of Medicine RxNorm project, is making headway in resolving this, but it has not been established as a recognized standard. We encourage the FDA to coordinate with the CMS as they revise their drug establishment registration and listing regulations to make the NDC number unique and more useful to informational databases. We believe that RxNorm and NDC should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be accepted as the drug identification standards for all federal initiatives. We are eager to see publication of a Preliminary Rule for the NDC system and establishment of the NDC database.

HIMSS recommends the development of a standard clinician dictionary of medications. While there is a standard for pharmacy packages (the NDC code), clinicians use different systems with different vocabularies. It is also recommended that the RxNorm project be accelerated and adopted as the standard medication vocabulary for E-Prescribing. We believe NDC and RxNorm should be mutually supportive and consistent. Together, the NDC packaging information and RxNorm vocabulary should be the drug identification standards accepted for E-Prescribing.

While RxNorm shows promise in providing semantic interoperability between systems using different proprietary drug databases, the use of RxNorm in real world E-Prescribing situations has not yet been established and needs to be tested for comprehensiveness. In particular, E-Prescribing transactions using RxNorm as a common orderable drug identifier need to be tested to ensure that the prescriber's intent can

be fully captured – especially when characteristics of a medication other than dose form, strength and chemical composition can impact the prescribing decision. Such characteristics include the presence of animal products in a medication or allergens such as egg products or preservatives situations where the patient is unable to consume such products for medical, personal or religious reasons.

HIMSS recommends that CMS conduct pilots to adequately test the ability of RxNorm to provide a bridge between prescribing systems using different databases, while fully communicating the prescriber's intent.

# HIPAA

**Summary of Proposed Rule**

Transactions subject to regulation under HIPAA standards, including those for privacy and security, must continue to comply with HIPAA standards. Providers are HIPAA-covered entities if they engage in electronic transactions for which there are HIPAA standards. If a provider was not otherwise a covered entity under HIPAA, the provider would become a covered entity if it conducts an E-Prescribing transaction that is also a HIPAA transaction, such as the 270/271 eligibility and response.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. The AOA should consider public announcements to ease the concerns of our patients in this regard.

## HIMSS' Response

HIMSS supports present federal HIPAA standards, including those for privacy and security. HIMSS interprets the present HIPAA rules as stating that any provider that is not otherwise a covered entity under HIPAA would become a covered entity if they conduct E-Prescribing transactions.

While HIPAA privacy standards are in place, the public concerns regarding access to, or dissemination of personally identifiable health information persist. HIMSS, therefore, recommends more aggressive educational programs for the public.

HIMSS also urges HHS to write federal HIPAA regulations to preempt more restrictive state privacy regulations whenever these state regulations would impede the implementation of E-Prescribing.

# NPRM

## Use of Standards In "Closed Enterprises"

**Summary of Proposed Rule**

CMS recognizes that many closed networks currently conduct E-Prescribing within the confines of their enterprise. Recommendations have been offered by NCVHS that closed enterprises should not be subject to the proposed E-Prescription Standards unless the prescription is sent outside the organization. The NCVHS recommendation is different from HIPAA transaction requirements; therefore, CMS is soliciting comment on whether they should adhere to the NCVHS recommendations or require closed enterprises to be compliant with the HIPAA transaction requirements.

## HIMSS' Response

HIMSS supports the principles espoused in section II. C of the NPRM with regard to continuing to allow "closed" enterprises to use whatever means they have in place for electronic transactions covered under the NPRM. We support the interpretation that Part D plans should not be required to use the standards defined in the regulation within the confines of an enterprise. Specifically, we recommend that the proposed language for Section 423.160 (a) (2) be amended not to apply to transactions within closed enterprises.

We specifically note that HL7 and NCPDP have worked together to ensure that the information content of HL7 and NCPDP SCRIPT transactions can be translated between the two standards for outpatient prescriptions. It is critical that entities be required to provide for interoperability for E-Prescribing with outside entities – even though they may choose to use proprietary methods within their enterprise. This interoperability is critical for the promotion of the NHIN, as well as the safe transfer of patient care from inpatient to outpatient settings. Many of the most serious and costly adverse drug reactions occur due to lack of accurate medication lists during patient transfers between hospitals and outpatient setting, resulting in duplicate or omitted medications.

The language in the NPRM regarding the exclusive use of NCPDP SCRIPT for the purposes of electronically transmitting a Medicare Part D prescription could be interpreted to mean that a provider entity (e.g., a hospital) using some other internal method for generating prescriptions electronically (e.g., a CPOE system using HL7) would be required to generate an NCPDP SCRIPT message for outpatient prescriptions without the use of an intermediary. While some larger provider organizations may be able to create their own means for translating these messages internally, many provider entities do not have these resources and would be dependent upon an intermediary to provide these services. As long as the receiving entity (e.g., the community pharmacy) receives a NCPDP SCRIPT message, there should be no restriction on the use of intermediaries for performing this translation. HIMSS requests that this appropriate use of intermediaries be clearly permitted in the final rule.

HIMSS also recommends that specific rules are included to prevent restrictions of choice of E-Prescribing software as well as patient choice for provider, pharmacy and medication so that optimum patient care is protected.

# National Provider Identifier

**Summary of Proposed Rule**

NCVHS found that it was important to address the issue of provider identifiers for various E-Prescribing standards it reviewed and, more generally, for an E-Prescribing drug program. They further recommend the use of National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available. The NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers can be used in the event that the National Provider System is not available in time for Medicare Part D E-Prescribing.

## HIMSS' Response

HIMSS shares CMS and NCVHS anticipation of broad-ranging benefits the industry will receive once the NPI becomes ubiquitous. Efforts urging for faster implementation of the NPI are supported by HIMSS. However, we have two concerns with the proposal to use NPI for E-Prescribing:

- NPIs will enumerate legal entities but it may be more useful to identify physical locations in E-Prescribing systems and processing; and

- NCPDP's Provider Identifier Number enumerates the dispenser's physical location, but a broader consideration of healthcare location enumeration may be warranted.

Both of these issues should be subject of careful study and pilot testing before CMS designates interim or final enumeration of dispensers and prescribers.

NPI will enumerate legal entities. This information is useful for many purposes, but identification of the dispenser's legal entity may not be the most useful identification for E-Prescribing. In fact, enumeration of physical location may be essential for the envisioned E-Prescribing. For providers, NPI may be ideal, but there must also be a mechanism for patients and dispensers to identify an authorized person for questions or other follow-up related to a prescription. Until they are implemented, we cannot know whether NPI enumeration will meet all functional requirements of E-Prescribing. HIMSS recommends that as part of the comprehensive assessment and pilots, the primary identifier for dispensers and prescribers be more carefully evaluated.

HIMSS further recommends that similar careful study and pilot testing be done of any interim enumeration of dispensers and prescribers. The NCPDP Provider Identifier Number, which enumerates dispensers, is widely used and seems effective for the current retail e-commerce. Its effectiveness for broader use in the envisioned MMA E-Prescribing environment should be evaluated and tested.

HIMSS is also concerned by the number of healthcare enumerators. A confusing collection of competing enumeration systems actually inhibits technology adoption. Fees increase healthcare costs without benefits to patient care. The Coalition for eHealth Standards (CHeS) has addressed this situation and recommends the EAN.UCC Global Location Identification Number (GLIN) for enumeration of locations of healthcare entities. In the pilot testing, HIMSS recommends consideration of GLIN for enumeration of dispensers and prescribers.

Whether NCPDP, GLIN, or another enumerator is selected, HIMSS requests that fees and maintenance costs of the identifier be added to the Regulatory Impact Analysis

## Interoperability

**Summary of Proposed Rule**

CMS acknowledges that E-Prescribing must be interoperable with other parts of an electronic health record (EHR) and that there is much support for postponing the adoption of standards for E-Prescribing until interoperability standards are developed for EHRs. CMS has chosen to proceed with E-Prescribing standards to take advantage of the obvious patient safety and healthcare quality benefits associated with E-Prescribing. CMS proposes foundation ANSI-accredited standards to begin the E-Prescribing process. CMS is convinced that E-Prescribing standards will spur interoperability standards for EHRs and other HIT hardware and software solutions.

## HIMSS' Response

While there is extensive industry experience in transmitting prescriptions electronically in general, the proposed foundational standards and the additional E-Prescribing requirements under MMA not addressed by the Foundation Standards have not been adequately tested together in a wide range of settings that represent healthcare delivery today. HIMSS requests that CMS conduct one or more pilots that incorporate all the Foundation Standards and the proposed additional standards in order to assess the overall impact of E-Prescribing on Medicare and the impact to E-Prescribing performed outside of Medicare.

Additionally, with respect to achieving interoperability between E-Prescribing tools, EHRs, and the entire HIT continuum, HIMSS offers to work with CMS to leverage the successes and findings from IHE. IHE is a multi-year, global initiative that creates the framework for passing vital health information seamlessly—from application to application, system to system, and setting to setting—across multiple healthcare enterprises. IHE brings together HIT stakeholders to implement standards for communicating patient information efficiently throughout and among healthcare enterprises by developing a framework for interoperability that is made available in the public domain. In its seven-year history, IHE has succeeded in engaging vendors and establishing implementation momentum. Hundreds of HIT, radiology, laboratory, and cardiology products have already successfully demonstrated support for IHE. Because of its proven process of collaboration, demonstration and real world implementation of interoperable solutions, IHE is in a unique position to significantly accelerate the process for defining, testing, and implementing the standards-based interoperability that is necessary for E-Prescribing and ultimately the President's goal of achieving widespread adoption of HIT solutions and ultimately the NHIN.

IHE has developed a unique process for producing its framework for interoperability by: (1) combining the collaboration of the primary stakeholders in an efficient and focused manner; (2) operating on a yearly cycle to ensure rapid and immediately applicable advances in HIT innovation; (3) providing practical tools and information resources in the public domain that facilitate adoption of standards-based integration solutions, and (4) enabling both healthcare entities and vendors to improve access to information incrementally.

HIMSS and its partner organizations, including the Radiological Society of North America (RSNA) and the American College of Cardiology (ACC) recommend the IHE process to the federal government for consideration in developing a role for the IHE process in its efforts to advance E-Prescribing and other pertinent HIT initiatives.

Finally, the HIMSS' Integration & Interoperability Steering Committee has been working on a proposed interoperability definition that may be useful to CMS. HIMSS is coordinating an industry-wide interoperability definition for later this summer and looks forward to the opportunity to showcase the completed product to CMS and our industry partners.

## Impact Analysis

**Summary of Proposed Rule**

Included as a requirement of the Regulatory Flexibility Act of 1980, the CMS impact analysis reviews the likely impact of the E-Prescribing regulation on the delivery of healthcare in the U.S., as well as on a number of healthcare constituencies, including health plans and pharmacy benefit managers (PBMs), clinician prescribers, pharmacies and dispensers, individual patients, and small businesses. CMS concludes that the E-Prescribing regulation will positively impact healthcare delivery, particularly in measurable clinical outcomes, cost reductions, and improvements in business processes. Impact analyses are based largely on testimony before NCVHS and documents in the public domain.

## HIMSS' Response

HIMSS concurs with the CMS assessment that E-Prescribing will have a positive impact on healthcare delivery in the U.S. Overall, we anticipate an increased interest in E-Prescribing as the inclusion of E-Prescribing provisions in MMA has already heightened awareness of the benefits the variety of devices and connectivity solutions available offers prescribers, along with the fact that many of the standards under consideration are already in use. Given the experiences of many of our members, we anticipate a reduction in adverse health events associated with anticipated improvements in prescription drug compliance as identified in previous sections of our response.

HIMSS' subject matter experts stress that E-Prescribing will be successful if all constituencies are empowered to participate in the process. To that end, HIMSS encourages CMS to continue interacting with the community-at-large as CMS develops the E-Prescribing program to ensure that the necessary tools and metrics are in place to provide appropriate and timely information to the provider. At every step along the chain of custody of an E-Prescription, measurements need to be in place to provide adequate incentives for implementation and long-term use by participants. Additionally, CMS must demonstrate that E-Prescribing will streamline clinician workflow and ensure the availability of necessary interoperability tools within and between systems to gain clinician buy-in.

HIMSS expects that, if the necessary business and clinical tools are in place, as many as 15-25% of physicians would elect to participate in the early stages of an MMA E-Prescribing Program with another 50% joining after a year or two. The last 25-35% may be very slow to participate and may eventually require other measures to encourage their participation.

Finally, HIMSS encourages CMS to address the issue of incentives to participate in the E-Prescribing program. A number of organizations within the healthcare continuum will participate based on community empowerment and federal regulation. However, HIMSS anticipates that a significant number of organizations will not participate until they receive adequate reimbursement through implementation funding, deferential reimbursement, or pay-for-performance.

## Conclusion

HIMSS enthusiastically shares in the vision for E-Prescribing as described in the NPRM. Relying on the subject matter expertise of our members, we were pleased to work through the process of responding to the proposed rule. We are pleased to have worked closely with the HIMSS Board of Directors and various entities within the HIMSS community to develop a response that is consistent with the views of our membership.

In summary, HIMSS is concerned that the Foundation Standards may not be adequately tested, and therefore recommend a pilot program to determine understanding and use of the Foundation Standards in real settings. Our membership would be pleased to discuss this issue further with CMS to ensure adequate metrics are collected during scheduled pilot programs.

We are also concerned that the National Provider Identifier has two essential limitations that need to be addressed by government and industry, including the decision to use a legal entity versus a physical location or healthcare location enumeration.

HIMSS is encouraged by the public discussion that CMS is considering exemptions for the Anti Kickback Act and Stark Regulations for HIT efforts between various entities. As we stated in the Collaborative Response to the ONCHIT RFI, complete interoperability of healthcare must be provided by any entity seeking a safe harbor. Establishing a Standards and Policy Entity would provide the means of assessing the need for safe harbors as information sharing networks are created, especially in meeting the needs of rural and underserved communities.

In closing, HIMSS would like to emphasize that interoperability will be an important component of the E-Prescribing and EHR implementation processes. HIMSS is confident that IHE will continue to help drive the healthcare industry toward interoperability. We look forward to continuing our excellent working

relationship with CMS, and to offering the collective voice of our membership as the proposed rule is finalized and the collaboration is underway.

HIMSS and our members look forward to continuing the necessary dialogue with CMS as we strive to achieve a successful rollout of the E-Prescribing program, from the pilot program through full implementation. If you need any additional information, please feel free to contact Thomas M. Leary, HIMSS Director of Federal Affairs, at tleary@himss.org or 703.299.9712.

**Submitter :** **Mr. Michael Simko** **Date: 04/05/2005**

**Organization :** **Walgreens**

**Category :** **Pharmacist**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-41-Attach-1.DOC

CMS-0011-P-41-Attach-2.DOC

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

***Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments***

Centers for Medicare and Medicaid Services:

The Walgreen Company is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Walgreens was founded in 1901. Walgreens operates more than 4700 stores in 45 states and Puerto Rico. Walgreens Drug Stores fill over 1 million prescriptions daily and account for 14% of all retail pharmacy prescriptions dispensed in the United States. Walgreens has been an active participant in eprescribing for over 10 years. Walgreens submits the following responses regarding the NPRM.

## I. Background (F. R. page 6257)

### *A. Statutory Basis*

*Although there is no requirement that providers write prescriptions electronically, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.*

*Section 1860D–4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is ''adequate industry experience.'' Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.*

**WALGREEN RESPONSE:**

**Walgreens agrees with and participated in the formation of the NCPDP response.**

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American

National Standards Institute (ANSI) accredited. There is concern that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

Walgreens supports the naming of standards as draft foundation standards and CMS should encourage adoption on a voluntary basis while these standards go through the ANSI-accredited Standards Development Organization. CMS should not mandate by law these draft foundation standards, until they have been approved. CMS should also not wait until the 2008/2009 dates to adopt these standards.

As pilots go through the testing phase, standards not currently adopted, as foundation standards may need to be changed and amended before final adoption. Because of the level of interoperability being suggested as eprescribing moves forward, Walgreens supports the ongoing evaluation of standards by NCVHS and wants to ensure the equal participation of all entities in the entire eHealth continuum.

Standards need to be dynamic and should be reviewed by an official group for ongoing relevancy, adoptibility, adaptability, and practicality.

***2. State Preemption (F.R. page 6259)***

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**WALGREENS RESPONSE:**

**Walgreens agrees with and participated in the formation of the NCPDP response.**

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable, national scheme, physicians and pharmacists will be uncertain as to their obligations with respect to Medicare-covered prescriptions as opposed to other electronic prescriptions which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic e-prescribing software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer (e.g., where multiple coverages exist, which coverage will be the ultimate payer under coordination of benefit rules).

"Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available or cannot make available because the determination of coverage isn't made until the actual script is filled and the claim is adjudicated. Patients with multiple benefit plans and secondary payers may present other problems at the point of care as well, such as which formulary and benefit information,. The rules affecting *how* electronic prescribing is done should not vary based on who the ultimate payer will be.

CMS stated in the preamble to the NPRM "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of State law that will require detailed analysis in all 50 states to determine whether existing State law should be read to mingle with Federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a State requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that State require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?
- Does a Medicare prescription transmitted electronically need to meet State rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable State forbids such intermediaries?
- Can the physician or pharmacist be disciplined under State law where a prescription is sent electronically according to the Federal rule but it is deficient for State law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer), which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of this ambiguity and confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

**We believe a single, national set of regulations for electronic prescribing is in the interest of all parties, including the states.** The principal concern of states would not likely be that the Federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that State Boards of Pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the State Boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- Transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- Rules relating to formatting of prescriptions and documentation of the prescriber's intent
- Rules relating to authentication of the prescriber and dispenser
- Rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of Federal and State laws affecting all electronic prescriptions.

The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a

broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant State law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as Federal standards are adopted for electronic prescriptions, they preempt any contrary State standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all State rules on those topics with respect to all electronic prescriptions.

As similar situations will exist with other pharmacy chains that have pharmacy operations across states, a single set of regulations governing eprescribing is essential for the interoperability of systems, such as EMR's, RHIO's, and NHIN. Variations across states in eprescribing regulations will be expensive to build, difficult to maintain, and will slow down adoption and implementation of eprescribing.

There should be federal preemption of contrary state regulations regarding eprescribing.

**Walgreens agrees with NCPDP's position on Long Term Care Setting**:

Regarding Long Term Care Settings:

1. Federal, State and insurance payers require paper verification of services rendered including physicians and other health care provider's non-electronic signatures. In order for e-prescribing to work in the LTC setting, the State and Federal survey processes must accept electronic records and signatures.
2. Due to the numerous changes in the level of care for beneficiaries in the nursing facility the e-prescribing model must be available for all payment types not only Medicare Part D. The LTC setting needs a uniform industry standard for e-prescribing.
3. These proposed rules do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different State specific regulations pertaining to the record keeping of controlled substance prescriptions. These State specific regulations are even more unique for the LTC pharmacies and facilities.

## E. Current E-Prescribing Environment (F.R. page 6260)

**WALGREEN RESPONSE – Walgreens supports and participated in the formation of NCPDP's response.**

NCPDP, at the request of industry participants, has created a new work group for Long Term Care. The scope of this work group is:

> Work Group 14 Long Term Care, in conjunction with the other Work Groups, guides and advises payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation, supports data processing initiatives, and provides design alternatives for standards used within the long term care industry

It is expected that long term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy.

1. In order for e-prescribing to work in the LTC setting the beneficiaries eligibility information must be real time. In the LTC setting, physicians and facility nurses do not know a patient's pharmacy benefits eligibility and coverage. The industry has relied on the LTC pharmacy provider to keep this information. The pharmacy and nursing facility-billing offices communicate patient billing status (inpatient or outpatient) which changes by the skilled level of care determined by the patient's medical conditions.
2. Due to the numerous levels of care changes of a beneficiary on a daily basis within a nursing facility, real time eligibility information must be available to the pharmacy and physician to handle the formulary and prior authorization processes within e-prescribing to meet the coordination of benefits (COB) between Medicare Part A, B and D.
3. Medical records for nursing facility patients are located at the nursing facility, not in the physician's office. This causes difficulty when the patients' information is needed from their medical chart. The information gathering process is often left up to the LTC nurses and pharmacists.
4. For e-prescribing to work efficiently in a LTC setting an electronic health record (EHR) is needed. There is an increased need for process adaptations and communication between these healthcare professionals in LTC to assure nursing facilities meet the required Federal regulation to provide prescribed medications to nursing home residents in a "timely manner".

### F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)

*We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions and we solicit comments on these criteria…*

**Walgreens Response:**

Please see response to section " ***I. Background (F. R. page 6257) A. Statutory Basis***".

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**WALGREENS RESPONSE:**
**Walgreens agrees with and participated in the formation of the NCPDP response.**

Attached is the NCPDP response. Walgreens supports version management and believes that there should be adequate version control by a recognized standard setting organization. The challenge will be for the critical mass of participants to be functioning on supportable version releases to ensure connectivity and interoperability. There are inherent problems with large version release gaps that may impede support of new fields, message lengths, and relied upon data elements.

Walgreens recognizes the impact strict version control may have on entities that do not own their own code and must rely on outside vendors for programming and support. To that extent - Walgreens believes that there should be sufficient flexibility and adequate start date notices for the implementation of new versions and the sun-setting of older versions**.**

There exists a need for all SDO's to communicate version changes in various systems with adequate notice to ensure equal participation and interoperability of necessary interfaces between entities.

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing.

With the suggested naming of NCPDP SCRIPT Standard Version 5.0 in this NPRM, the industry will begin looking at this version, if they are not already supporting it. It is anticipated that industry participants will actually look at later versions of NCPDP SCRIPT Standard and implement these, since the modifications are not major, and then be able to support version 5.0 and above. It is also important to not negatively impact the traction of the current e-prescribing environment by naming a version the industry is not able to support timely. NCPDP SCRIPT

An NPRM on versioning methodology that is separate from this current e-prescribing NPRM may be required be for adopting this or a similar methodology. But the overall goal of this methodology would be to avoid the formal rulemaking process when introducing new versions of a standard while still allowing for a fully open process.

Walgreens suggests this process be followed for the NCPDP standards (and potentially other standards) named as part of the MMA or named in the future. The process would be invoked when the industry requests a new version of any of the NCPDP standards named as part of the MMA (excluding standards already named in HIPAA), or a new standard to be named. Walgreens also suggests that HHS consider using this process for advancing HIPAA named standards. The timings suggested above – such as the NCVHS reporting process – would have to be reviewed for feasibility and resource requirements. It may be better; for example, that NCVHS serve as the public announcement vehicle, but that the actual open forum is held by HHS or by the SDO itself.

An alternative step might be to schedule a regular, predictable cycle for holding hearings on submitting or retiring versions of a standard, for example. We welcome the opportunity to work with HHS to hone these concepts further so that they meet the needs of all stakeholders, comply with Federal law, and ultimately result in advancing patient care.

### G. Electronic Prescription Drug Program (F.R. page 6261)

**WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE:**

Within the proposed rules the impact on the Nursing Facility, LTC Pharmacies or Physicians serving Nursing Facilities is not addressed, as related to the MMA.

1. In the LTC setting there is a need to develop technology for a three-way communication between off site physicians, nursing facility medical record and LTC provider pharmacies. Have some incentives for nursing facility staff for training of high turnover nursing staff and access to computers for data entry. Nursing facilities have very few computer workstations and are still using a very manual charting process.
2. Prescription Drug Plans (PDP), LTC pharmacies, physicians and nursing facilities may incur additional costs different than the ambulatory setting since a more complex process of a three-way communication must be developed for an e-prescribing model to be successful in the LTC setting.
3. If the LTC setting is excluded from an e-prescribing process, this could add a strain to the physicians who have ambulatory and nursing facility patients.

**(F.R. page 6263)**
*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH THE NCPDP RESPONSE.**

The NCPDP Provider ID is the current de facto standard pharmacy identifier used for both the NCPDP Telecommunication Standard Version 5.1 and the NCPDP SCRIPT Standard. Both of these standards will support the use of the NPI to identify the dispenser. Industry is only now analyzing the system changes necessary for industry to begin using the NPI for HIPAA named transactions. No analysis has been done to assess the impact of using the NPI as a standard identifier for pharmacies in electronic prescribing. It is not likely that pharmacies will realize any positive financial impact of making this change and doing so may slow voluntary adoption. Therefore, NCPDP believes since the use of the NPI for this purpose has not been proven, its use should not be accelerated.

The NPI and the NPPES were not designed with electronic prescribing in mind. For example, an NPI may be assigned to organizations and subparts, but organizations cannot prescribe, only people. Additionally, some prescribers are not currently required to obtain an NPI under the HIPAA regulations. If the NPI is named as a standard for electronic prescribing, it is imperative that all prescribers including those not sending or receiving HIPAA transactions be required to obtain an NPI. Allowing an alternative identifier for prescribers that do not need to obtain an NPI under HIPAA would only result in the need to support multiple identifiers, which is contrary to administrative simplification.

Because the NPI and the NPPES were not designed with electronic prescribing in mind, industry will need to devise other methods of determining routing instructions for prescribers with multiple practice addresses if used. Industry will also need to determine whether a given NPI is that of a prescriber or an organization. The use of proprietary databases mapping the NPI to routing information and providing other information needed for authentication will be critical to successful messaging. These mechanisms are not currently in place as the numbers currently used by industry support multiple practice addresses and only enumerate prescribers.

The NPI is not meant to replace the DEA number or the Taxpayer Identifying Number that were established for purposes other than the purpose of the NPI and careful consideration must be given to using the NPI for this new purpose.

NCPDP suggests that (1) both the NPI and the NCPDP HCIdea® prescriber identifier be utilized in pilot programs to determine the applicability of each of the identifiers, that (2) a standard identifier for prescribers be named only after there is adequate industry experience in the use of the named identifier and that if the NPI is the named standard, (3) acceptable business practices are available for distribution of the NPI file to the industry. Until that time, we suggest the e-prescribing industry continue to use existing identifiers that support business purposes that the NPI currently does not support, such as transaction routing to specific locations.

**(F.R. page 6263)**
*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

**WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE.**

There is adequate industry experience in using the NCPDP Provider Identifier Number for identifying dispensers. NCPDP recommends that this identifier should be supported until such time as the NPI has proven to be a successful identifier for electronic prescribing. To require the use of the NPI to identify dispensers for electronic prescribing prior to successful pilot testing would be a disservice to e-prescribing and may slow voluntary adoption.

In identifying prescribers, NCPDP suggests that both the NPI and NCPDP HCIdea® are included in pilot tests and that the standard identifier best suited for electronic prescribing is selected for that purpose. If not selected as the standard prescriber identifier for e-prescribing, the HCIdea® Database may prove to be useful as a bridge for dispensers between the DEA, the NPI, and other identifiers currently used for prescriber identification. This bridge or cross walk between the NCPDP HCIdea®, the NPI, the DEA and other possible identifiers such as State license number and UPIN number may support healthcare organizations in populating their prescriber files with the proper NPI for each prescriber, linking one prescriber to multiple practice addresses and routing SCRIPT messages to the proper practice address (which can not be done with the NPI alone).

**Formulary and Medication History Standards (F.R. page 6263)**
*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*

**WALGREENS RESPONSE:**

Testimony to NCVHS showed industry experience. Medication History Standard has been brought forth to NCPDP and is being balloted. The Formulary and Benefit Standard has been brought forth to NCPDP and upon approval, will be taken to ballot. As with any standard, if business needs are brought forward, they will be discussed and taken through the approval process.

**(F.R. page 6263)**
*We propose the following critical characteristics for formulary and benefit data standards:*
**WALGREENS RESPONSE: SEE ABOVE**
See above.
**(F.R. page 6263)**
**We WALGREENS RESPONSE: SEE ABOVE**
See above.

**Drug Information (F.R. Page 6264)**
*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*

**WALGREENS RESPONSE:**

Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. Access to referential electronic drug information should be part of the overall physician practice management system and access to this type of information should not hinder the exchange of e-prescribing data. The availability and type of drug information made available to the prescriber should be determined by the prescriber's practice setting and individual needs.

### H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

*• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

**WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF NCPDP'S RESPONSE.**

WALGREENS supports these foundation standards. WALGREENS recommends that the minimum standard be the version named and that other higher versions, if backward compatible, are also acceptable, except where HIPAA supercedes this Final Rule. Please see response at section ***"F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)"***, where it is recommended that consideration for changes be given to HIPAA-named transactions**.**

The completed NCVHS Standards Worksheet indicated several gaps in the ASC X12N 270/271 Eligibility Inquiry and Response Standard. The near term solution proposed

> *"Where there are gaps in the information that needs to be transmitted in the 271 response (such as the need for formulary or benefit identifiers) the transaction does have a free form message segment that could outline the details that cannot currently be codified."*

Until the long-term solution is adopted under HIPAA, NCPDP requests the ASC X12N 270/271 Workgroup publish a document that outlines the details on how to use the free form message. The benefit of the document is a consistent implementation of the free form message.

**(F.R. Page 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**WALGREENS RESPONSE:**

There is no benefit to impeding the momentum driving the adoption of e-prescribing nor the development and implementation of standards for e-prescribing. E-prescribing and EHRs can exist both in an integrative and independent fashion. EHR is very broad and may be implemented in different timeframes and may be driven by different business and clinical needs. E-prescribing is available today and is being used in many clinical settings. As functionality is available, it should be incorporated into the whole continuum of care; but do not postpone implementation of the parts that are available today.

The simultaneous growth and emergence of both systems can occur at various stages independent of each other. There should be no "halt" in eprescribing development. HER is not yet "well defined" and will probably emerge more slowly than eprescribing connectivity.

## II. Provisions of the Proposed Regulation (F.R. Page 6264)

### B. Proposed Definitions (F.R. Page 6265)

- *Dispenser means a person, or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.*
- *Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.*
- *E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.*
- *Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.*
- *Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.*
- *Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information or a Part D eligible individual enrolled in a Part D plan.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.**

Walgreens supports the definition of e-prescribing. E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information.

Non-EDI Messages (e.g., Faxes or Emails)

Messages that leave or enter the system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions.

Walgreens supports the definition of electronic media.

Walgreens recommends the definition of Prescriber be expanded to authorized prescribers of drugs for human or animal use.

### C. Proposed Requirements for Part D Plans (F.R. Page 6265)

**(F.R. Page 6265)**

*We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted*
*e-prescribing standards.*

**WALGREENS RESPONSE:**

Standards should be used when transmitting outside of the enterprise and the inter-connection of separate systems.

### E. Proposed Standards (F.R. Page 6265)

*We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

**WALGREENS RESPONSE:**

Walgreens trading partners using these transactions, especially in the 2006 pilots. Walgreens supports this approach

**(F.R. Page 6265)**

*We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:*
*• New prescription transaction*
*• Prescription refill request and response transactions*
*• Prescription change request and response transactions*
*• Cancel prescription request and response transactions*
*• The following ancillary messaging and administrative transactions:*
*+Get message transaction*
*+Status response transaction*
*+Error response transaction*
*+Verification transaction*
*+Password change transaction*

**WALGREENS RESPONSE:**

Walgreens supports these transactions being adopted.

**(F.R. Page 6266)**

*We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.*

**WALGREENS RESPONSE: Walgreens agrees with and participated in the formation of NCPDP's response.**

There is a difference between "adopt" and "require". NCPDP prefers CMS adopt these different transactions, but not require them unless the business need or the technology solution is demonstrated. For example, if a provider is connected via the internet/leased line/frame relay, they may not need to support GETMSG mailboxing functions. Why require it when they do not need it?

There is industry experience with STATUS and ERROR. The STATUS and ERROR messages are used today, and these are part of the "real-time" request and response environment of transaction processing. The STATUS and ERROR messages perform transactional functionality; this is different than the housekeeping transactions.

The GETMSG and PASCHG are housekeeping functions. There is adequate industry experience with GETMSG and PASCHG, for those entities needing the functionality.

GETMSG and PASCHG are in a sense internal messages: they flow only between a provider and his mailboxing service (e.g., aggregator), not from one provider to another. Thus, an aggregator may never see GETMSGs from prescribers or an aggregator may never see GETMSGs from pharmacies (depending on the relationship of the technology between the aggregator and the provider). In some instances where a partner does not have a static IP address and "listening capabilities" the GETMSG and PASCHG are being used.

VERIFY is a return receipt function. VERIFY is only used when someone needs it (much like requesting return receipt at USPS; not all mail needs return receipt). The VERIFY message may be used by the end users and sometimes by network partners. There is industry experience using VERIFY, although it should not be a required function as it is not a business function transaction, but rather a special case transaction.

### 2. Eligibility (F.R. Page 6266)

*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

**WALGREENS RESPONSE:**

The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

A clarification. The NCPDP Telecommunication Standard is EDI and was named in HIPAA. It does not adhere to EDIFACT or ASC standards. The NCPDP Telecommunication Standard was named in HIPAA for eligibility between pharmacies and payers. The pharmacy industry will be using the Telecommunication Standard for eligibility checking under MMA, especially in determining coordination of benefits information.

E-prescribing should not be hindered by the length of time that modifications are adopted in HIPAA named transactions.

**(F.R. Page 6267)**
*If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the* ***Federal Register*** *of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

**WALGREENS RESPONSE:**

Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

**(F.R. Page 6267)**
*We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

**WALGREENS RESPONSE:**
Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

## IV. Regulatory Impact Analysis (F.R. Page 6268)

*We invite public comment on our expectations for prescriber participation.*

**WALGREENS RESPONSE:**
Please see NCPDP's response at section " ***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)**
*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.**

The NPI is not in use today and the impact on pharmacies of adopting the NPI as an identifier for the electronic Prescriber may not be positive. Prescribers are defined as people and NPIs are to be assigned to places as well as people. The NPPES was not designed with e-prescribing in mind. Some Prescribers do not submit HIPAA transactions and will not have NPIs. The impact could well be negative if the NPI is not piloted and electronic prescriptions are received by pharmacies from places.

It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new standards and new versions of the standards must be predictable and timely (i.e., sensitive to current industry adoption capabilities)

so as not to negatively impact the movement of the industry as it addresses new business functions and needs.

**E. Impact on Patients (F.R. Page 6271)**

**WALGREENS RESPONSE:**

We agree that the adoption of electronic prescribing will have a net positive impact on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance.

**G. Impact on Small Businesses (F.R. Page 6271)**

*Accordingly, we conclude that this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. We welcome comments on this conclusion and additional information on the small business effects of this proposed rule.*

**WALGREENS RESPONSE:**

Participants of NCPDP noted that small businesses, independent pharmacies; small prescriber environments are already using SCRIPT. We are not aware of other studies and agree that more studies will need to be funded to assess and evaluate the overall impact on each of the participant entities. These would be valuable to the industry as a whole.

**H. Effects on States and Federalism Statement (F.R. Page 6272)**

**WALGREENS RESPONSE:**

Please see response at section "***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**I. Conclusions and Alternatives Considered (F.R. Page 6272)**

*We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

**WALGREENS RESPONSE:**

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard. Please see comments in Section *"G. Electronic Prescription Drug Program (F.R. page 6261)."* Walgreens believes that the NCPDP HCIdea prescriber identifier, which enumerates prescribers and not places, should be piloted as an alternative to the NPI for e-prescribing applications if needed. Careful consideration needs to avoid undue burden on pharmacy systems and prescribers in implementing too complex a message routing format.

**(F.R. Page 6273)**

*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*

**WALGREENS RESPONSE:**

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard, and the Formulary and Benefit Standard.

**PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard.

Conclusion:

Walgreens supports an eprescribing system – including EMR's that allows rapid adoption by all participating entities utilizing proven industry standards such as NCPDP Script. While foundation standards can be initially implemented, attention must be paid to adapting standards in a structured way that is fair to all participants in a practical timeframe without slowing down the adoption of eprescribing and EMR implementation.

Walgreens believes in the preemption in contrary State pharmacy regulations concerning eprescribing. These will only hinder adoption and slow the process of gaining the patient safety and improvement of care benefits EMR's and eprescribing will bring.

Thank-you

Michael J. Simko, R.Ph.
Manager – Pharmacy health Information Technology
Walgreens
200 Wilmot Road
Deerfield, IL 60015
(847) 914-3157

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

***Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments***

Centers for Medicare and Medicaid Services:

The Walgreen Company is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Walgreens was founded in 1901. Walgreens operates more than 4700 stores in 45 states and Puerto Rico. Walgreens Drug Stores fill over 1 million prescriptions daily and account for 14% of all retail pharmacy prescriptions dispensed in the United States. Walgreens has been an active participant in eprescribing for over 10 years. Walgreens submits the following responses regarding the NPRM.

## I. Background (F. R. page 6257)

### *A. Statutory Basis*

*Although there is no requirement that providers write prescriptions electronically, in the Medicare Prescription Drug Benefit final rule, we stated that Part D sponsors that participate in the Part D program are required to support and comply with electronic prescribing. Providers that prescribe or dispense Part D drugs would be required to comply with the final standards only when prescription information or certain other related information is electronically transmitted once the final standards for those transactions are effective, which we anticipate will be in 2006, for this first set of final standards.*

*Section 1860D–4(e) of the Act specifies that initial standards, which are to be used in a pilot project that is to be conducted in calendar year 2006, must be adopted not later than September 1, 2005. This section of the Act also provides, however, that pilot testing is not required for those standards for which the Secretary, after consultation with affected standard setting organizations and industry users, determines there is ''adequate industry experience.'' Subsequent to the pilot project, the Secretary must promulgate final uniform standards not later than April 1, 2008. Those final uniform standards must become effective not later than 1 year after the date of promulgation of those final uniform standards. In addition, the Secretary is required to provide a report to the Congress by April 1, 2007 on his evaluation of the pilot project.*

**WALGREEN RESPONSE:**

**Walgreens agrees with and participated in the formation of the NCPDP response.**

Section 1860D-4(e)(4)(C)(ii) of the Act permits an exception to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. This establishes a subjective test to be applied by the Secretary and establishes a reasonable level of consultation for which the Secretary is responsible. However, the preamble to the NPRM proposes to adopt three criteria to assess adequate industry experience, the first being that the standard is American

National Standards Institute (ANSI) accredited. There is concern that in some cases awaiting ANSI accreditation may create timing issues that slow the process for implementing standards for e-prescribing unnecessarily.

Walgreens supports the naming of standards as draft foundation standards and CMS should encourage adoption on a voluntary basis while these standards go through the ANSI-accredited Standards Development Organization. CMS should not mandate by law these draft foundation standards, until they have been approved. CMS should also not wait until the 2008/2009 dates to adopt these standards.

As pilots go through the testing phase, standards not currently adopted, as foundation standards may need to be changed and amended before final adoption. Because of the level of interoperability being suggested as eprescribing moves forward, Walgreens supports the ongoing evaluation of standards by NCVHS and wants to ensure the equal participation of all entities in the entire eHealth continuum.

Standards need to be dynamic and should be reviewed by an official group for ongoing relevancy, adoptibility, adaptability, and practicality.

***2. State Preemption (F.R. page 6259)***

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**WALGREENS RESPONSE:**

**Walgreens agrees with and participated in the formation of the NCPDP response.**

We believe the proposed interpretation of Section 1860D-4(e)(5) of the Act is unnecessarily narrow and, by creating a scheme that applies only to Medicare-covered prescriptions as an overlay on the current 50-state scheme for regulating electronic prescribing, will severely undermine the success of the electronic prescribing program envisioned by the Act. Without creating a clearer, more predictable, national scheme, physicians and pharmacists will be uncertain as to their obligations with respect to Medicare-covered prescriptions as opposed to other electronic prescriptions which will impact their willingness to participate in electronic prescribing. Without adoption, the benefits of electronic prescribing cannot be realized.

The interpretation proposed in the NPRM creates a system whereby the prescriber, and the electronic e-prescribing software vendor with which the prescriber is affiliated, must answer coverage questions before knowing whether to apply the standards promulgated under the Act - questions which are not currently answered by the prescriber and for which there are no processes in place to answer (e.g., where multiple coverages exist, which coverage will be the ultimate payer under coordination of benefit rules).

"Standards" for electronic prescribing are meaningless if they only apply to a subset of prescriptions for any given drug, and will be extremely difficult to put into practice if applying them requires information at the point of prescribing which the current system does not make available or cannot make available because the determination of coverage isn't made until the actual script is filled and the claim is adjudicated. Patients with multiple benefit plans and secondary payers may present other problems at the point of care as well, such as which formulary and benefit information,. The rules affecting *how* electronic prescribing is done should not vary based on who the ultimate payer will be.

CMS stated in the preamble to the NPRM "there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted." Interpreting the Congressional mandate in this limited manner sets up a system of partial preemption of State law that will require detailed analysis in all 50 states to determine whether existing State law should be read to mingle with Federal rules. Clearly this will create great confusion and innumerable questions of interpretation. For example,

- If a State requires a digital signature for purposes of authenticating an electronic prescription, but the Federal rule does not yet speak to authentication issues, does a Medicare prescription transmitted electronically to a pharmacy in that State require a digital signature to be valid, even where transmitted according to the Federal standard?
- What happens where there is dual coverage between Medicare and a commercial payer?
- Does a Medicare prescription transmitted electronically need to meet State rules relating to the format of prescriptions (e.g., rules relating to the communication of "dispense as written" in certain specific ways)?
- If a Medicare prescription is transmitted electronically according to the Federal rule, is the pharmacist at risk for filling it if it was transmitted with the assistance of an intermediary or switch where the applicable State forbids such intermediaries?
- Can the physician or pharmacist be disciplined under State law where a prescription is sent electronically according to the Federal rule but it is deficient for State law purposes? Will physicians feel comfortable sending such prescriptions where the deficiency depends on a coverage rule (i.e., whether Medicare is the payer), which can only be applied when the claim is adjudicated? How will uncertainty among physicians and pharmacists about their professional obligations affect their willingness to adopt and use this technology?

The likely result of this ambiguity and confusion is that adoption of electronic prescribing will be significantly slowed while the industry works through the uncertainty. We believe that the statutory language adopted by Congress allows for a broader reading, and that HHS should make every effort to propose standards and rules of applicability that would in fact provide for a clear, predictable, national scheme for all electronic prescriptions.

**We believe a single, national set of regulations for electronic prescribing is in the interest of all parties, including the states.** The principal concern of states would not likely be that the Federal standards are preemptive with respect to electronic prescriptions, but that the standards are sufficiently broad so as to address all of the concerns that State Boards of Pharmacy typically seek to address in their rules. While the National Association of Boards of Pharmacy and the State Boards themselves are better equipped to provide input on breadth of issues that the standards must address, we believe the issues fall into four primary categories:

- Transaction standards relating to the transmission of prescriptions and prescription information among interested parties
- Rules relating to formatting of prescriptions and documentation of the prescriber's intent
- Rules relating to authentication of the prescriber and dispenser
- Rules relating to the security of the transmission of prescription information and the applicable prescription from the prescriber to the pharmacy of the patient's choice

Addressing all of these issues with a single, national, comprehensive set of regulations applicable to all electronic prescriptions would provide a clear path for all prescribers seeking to participate in electronic prescribing while eliminating the risks inherent in having a complex set of Federal and State laws affecting all electronic prescriptions.

The NPRM only addressed the first issue, transaction standards, and seeks to limit the scope of the proposed "standards" to only prescriptions prescribed for Medicare covered individuals. Taking a

broader view of preemption and applying the proposed transaction standards to all electronic prescriptions would not create significant State law issues, but would start down a path toward a workable solution that meets the goals that Congress intended when taking up electronic prescribing in the MMA.

Achieving this goal, however, does not require the Secretary to abandon taking a phased approach to the adoption of standards. The most important thing at this stage is for it to be clear that as Federal standards are adopted for electronic prescriptions, they preempt any contrary State standard with respect to all electronic prescriptions. With this approach, the transaction standards proposed in the NPRM could be adopted and applied to all electronic prescriptions, while continuing to leave to the states the implementation of rules addressing the other three categories of concerns listed above. Thereafter, as the Secretary is prepared to implement comprehensive rules relating to these other areas, then those rules would preempt all State rules on those topics with respect to all electronic prescriptions.

As similar situations will exist with other pharmacy chains that have pharmacy operations across states, a single set of regulations governing eprescribing is essential for the interoperability of systems, such as EMR's, RHIO's, and NHIN. Variations across states in eprescribing regulations will be expensive to build, difficult to maintain, and will slow down adoption and implementation of eprescribing.

There should be federal preemption of contrary state regulations regarding eprescribing.

**Walgreens agrees with NCPDP's position on Long Term Care Setting**:

Regarding Long Term Care Settings:

1. Federal, State and insurance payers require paper verification of services rendered including physicians and other health care provider's non-electronic signatures. In order for e-prescribing to work in the LTC setting, the State and Federal survey processes must accept electronic records and signatures.
2. Due to the numerous changes in the level of care for beneficiaries in the nursing facility the e-prescribing model must be available for all payment types not only Medicare Part D. The LTC setting needs a uniform industry standard for e-prescribing.
3. These proposed rules do not address the fact that the Drug Enforcement Agency (DEA) has not adopted e-prescribing regulations for controlled substances. There are numerous different State specific regulations pertaining to the record keeping of controlled substance prescriptions. These State specific regulations are even more unique for the LTC pharmacies and facilities.

## E. Current E-Prescribing Environment (F.R. page 6260)

**WALGREEN RESPONSE – Walgreens supports and participated in the formation of NCPDP's response.**

NCPDP, at the request of industry participants, has created a new work group for Long Term Care. The scope of this work group is:

> Work Group 14 Long Term Care, in conjunction with the other Work Groups, guides and advises payers and providers of the long term care industry and institutional pharmacy programs and their agents on standards implementation, supports data processing initiatives, and provides design alternatives for standards used within the long term care industry

It is expected that long term care participants will be bringing standards requirements forward through NCPDP for the electronic prescribing environment, as their workflow and needs are different than community pharmacy.

1. In order for e-prescribing to work in the LTC setting the beneficiaries eligibility information must be real time. In the LTC setting, physicians and facility nurses do not know a patient's pharmacy benefits eligibility and coverage. The industry has relied on the LTC pharmacy provider to keep this information. The pharmacy and nursing facility-billing offices communicate patient billing status (inpatient or outpatient) which changes by the skilled level of care determined by the patient's medical conditions.
2. Due to the numerous levels of care changes of a beneficiary on a daily basis within a nursing facility, real time eligibility information must be available to the pharmacy and physician to handle the formulary and prior authorization processes within e-prescribing to meet the coordination of benefits (COB) between Medicare Part A, B and D.
3. Medical records for nursing facility patients are located at the nursing facility, not in the physician's office. This causes difficulty when the patients' information is needed from their medical chart. The information gathering process is often left up to the LTC nurses and pharmacists.
4. For e-prescribing to work efficiently in a LTC setting an electronic health record (EHR) is needed. There is an increased need for process adaptations and communication between these healthcare professionals in LTC to assure nursing facilities meet the required Federal regulation to provide prescribed medications to nursing home residents in a "timely manner".

### F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)

*We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions and we solicit comments on these criteria…*

**Walgreens Response:**

Please see response to section " ***I. Background (F. R. page 6257) A. Statutory Basis***".

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**WALGREENS RESPONSE:**
**Walgreens agrees with and participated in the formation of the NCPDP response.**

Attached is the NCPDP response. Walgreens supports version management and believes that there should be adequate version control by a recognized standard setting organization. The challenge will be for the critical mass of participants to be functioning on supportable version releases to ensure connectivity and interoperability. There are inherent problems with large version release gaps that may impede support of new fields, message lengths, and relied upon data elements.

Walgreens recognizes the impact strict version control may have on entities that do not own their own code and must rely on outside vendors for programming and support. To that extent - Walgreens believes that there should be sufficient flexibility and adequate start date notices for the implementation of new versions and the sun-setting of older versions**.**

There exists a need for all SDO's to communicate version changes in various systems with adequate notice to ensure equal participation and interoperability of necessary interfaces between entities.

As testifiers noted, the use of the NCPDP SCRIPT Standard in e-prescribing is growing.

With the suggested naming of NCPDP SCRIPT Standard Version 5.0 in this NPRM, the industry will begin looking at this version, if they are not already supporting it. It is anticipated that industry participants will actually look at later versions of NCPDP SCRIPT Standard and implement these, since the modifications are not major, and then be able to support version 5.0 and above. It is also important to not negatively impact the traction of the current e-prescribing environment by naming a version the industry is not able to support timely. NCPDP SCRIPT

An NPRM on versioning methodology that is separate from this current e-prescribing NPRM may be required be for adopting this or a similar methodology. But the overall goal of this methodology would be to avoid the formal rulemaking process when introducing new versions of a standard while still allowing for a fully open process.

Walgreens suggests this process be followed for the NCPDP standards (and potentially other standards) named as part of the MMA or named in the future. The process would be invoked when the industry requests a new version of any of the NCPDP standards named as part of the MMA (excluding standards already named in HIPAA), or a new standard to be named. Walgreens also suggests that HHS consider using this process for advancing HIPAA named standards. The timings suggested above – such as the NCVHS reporting process – would have to be reviewed for feasibility and resource requirements. It may be better; for example, that NCVHS serve as the public announcement vehicle, but that the actual open forum is held by HHS or by the SDO itself.

An alternative step might be to schedule a regular, predictable cycle for holding hearings on submitting or retiring versions of a standard, for example. We welcome the opportunity to work with HHS to hone these concepts further so that they meet the needs of all stakeholders, comply with Federal law, and ultimately result in advancing patient care.

### G. Electronic Prescription Drug Program (F.R. page 6261)

**WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE:**

Within the proposed rules the impact on the Nursing Facility, LTC Pharmacies or Physicians serving Nursing Facilities is not addressed, as related to the MMA.

1. In the LTC setting there is a need to develop technology for a three-way communication between off site physicians, nursing facility medical record and LTC provider pharmacies. Have some incentives for nursing facility staff for training of high turnover nursing staff and access to computers for data entry. Nursing facilities have very few computer workstations and are still using a very manual charting process.
2. Prescription Drug Plans (PDP), LTC pharmacies, physicians and nursing facilities may incur additional costs different than the ambulatory setting since a more complex process of a three-way communication must be developed for an e-prescribing model to be successful in the LTC setting.
3. If the LTC setting is excluded from an e-prescribing process, this could add a strain to the physicians who have ambulatory and nursing facility patients.

**(F.R. page 6263)**
*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH THE NCPDP RESPONSE.**

The NCPDP Provider ID is the current de facto standard pharmacy identifier used for both the NCPDP Telecommunication Standard Version 5.1 and the NCPDP SCRIPT Standard. Both of these standards will support the use of the NPI to identify the dispenser. Industry is only now analyzing the system changes necessary for industry to begin using the NPI for HIPAA named transactions. No analysis has been done to assess the impact of using the NPI as a standard identifier for pharmacies in electronic prescribing. It is not likely that pharmacies will realize any positive financial impact of making this change and doing so may slow voluntary adoption. Therefore, NCPDP believes since the use of the NPI for this purpose has not been proven, its use should not be accelerated.

The NPI and the NPPES were not designed with electronic prescribing in mind. For example, an NPI may be assigned to organizations and subparts, but organizations cannot prescribe, only people. Additionally, some prescribers are not currently required to obtain an NPI under the HIPAA regulations. If the NPI is named as a standard for electronic prescribing, it is imperative that all prescribers including those not sending or receiving HIPAA transactions be required to obtain an NPI. Allowing an alternative identifier for prescribers that do not need to obtain an NPI under HIPAA would only result in the need to support multiple identifiers, which is contrary to administrative simplification.

Because the NPI and the NPPES were not designed with electronic prescribing in mind, industry will need to devise other methods of determining routing instructions for prescribers with multiple practice addresses if used. Industry will also need to determine whether a given NPI is that of a prescriber or an organization. The use of proprietary databases mapping the NPI to routing information and providing other information needed for authentication will be critical to successful messaging. These mechanisms are not currently in place as the numbers currently used by industry support multiple practice addresses and only enumerate prescribers.

The NPI is not meant to replace the DEA number or the Taxpayer Identifying Number that were established for purposes other than the purpose of the NPI and careful consideration must be given to using the NPI for this new purpose.

NCPDP suggests that (1) both the NPI and the NCPDP HCIdea® prescriber identifier be utilized in pilot programs to determine the applicability of each of the identifiers, that (2) a standard identifier for prescribers be named only after there is adequate industry experience in the use of the named identifier and that if the NPI is the named standard, (3) acceptable business practices are available for distribution of the NPI file to the industry. Until that time, we suggest the e-prescribing industry continue to use existing identifiers that support business purposes that the NPI currently does not support, such as transaction routing to specific locations.

**(F.R. page 6263)**
*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

**WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF THE NCPDP RESPONSE.**

There is adequate industry experience in using the NCPDP Provider Identifier Number for identifying dispensers. NCPDP recommends that this identifier should be supported until such time as the NPI has proven to be a successful identifier for electronic prescribing. To require the use of the NPI to identify dispensers for electronic prescribing prior to successful pilot testing would be a disservice to e-prescribing and may slow voluntary adoption.

In identifying prescribers, NCPDP suggests that both the NPI and NCPDP HCIdea® are included in pilot tests and that the standard identifier best suited for electronic prescribing is selected for that purpose. If not selected as the standard prescriber identifier for e-prescribing, the HCIdea® Database may prove to be useful as a bridge for dispensers between the DEA, the NPI, and other identifiers currently used for prescriber identification. This bridge or cross walk between the NCPDP HCIdea®, the NPI, the DEA and other possible identifiers such as State license number and UPIN number may support healthcare organizations in populating their prescriber files with the proper NPI for each prescriber, linking one prescriber to multiple practice addresses and routing SCRIPT messages to the proper practice address (which can not be done with the NPI alone).

**Formulary and Medication History Standards (F.R. page 6263)**
*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*

**WALGREENS RESPONSE:**

Testimony to NCVHS showed industry experience. Medication History Standard has been brought forth to NCPDP and is being balloted. The Formulary and Benefit Standard has been brought forth to NCPDP and upon approval, will be taken to ballot. As with any standard, if business needs are brought forward, they will be discussed and taken through the approval process.

**(F.R. page 6263)**
*We propose the following critical characteristics for formulary and benefit data standards:*
**WALGREENS RESPONSE: SEE ABOVE**
See above.
**(F.R. page 6263)**
**We WALGREENS RESPONSE: SEE ABOVE**
See above.

**Drug Information (F.R. Page 6264)**
*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*

**WALGREENS RESPONSE:**

Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. Access to referential electronic drug information should be part of the overall physician practice management system and access to this type of information should not hinder the exchange of e-prescribing data. The availability and type of drug information made available to the prescriber should be determined by the prescriber's practice setting and individual needs.

### H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

*• The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*• The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*• The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

**WALGREENS RESPONSE: WALGREENS AGREES WITH AND PARTICIPATED IN THE FORMATION OF NCPDP'S RESPONSE.**

WALGREENS supports these foundation standards. WALGREENS recommends that the minimum standard be the version named and that other higher versions, if backward compatible, are also acceptable, except where HIPAA supercedes this Final Rule. Please see response at section ***"F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)"***, where it is recommended that consideration for changes be given to HIPAA-named transactions**.**

The completed NCVHS Standards Worksheet indicated several gaps in the ASC X12N 270/271 Eligibility Inquiry and Response Standard. The near term solution proposed

> *"Where there are gaps in the information that needs to be transmitted in the 271 response (such as the need for formulary or benefit identifiers) the transaction does have a free form message segment that could outline the details that cannot currently be codified."*

Until the long-term solution is adopted under HIPAA, NCPDP requests the ASC X12N 270/271 Workgroup publish a document that outlines the details on how to use the free form message. The benefit of the document is a consistent implementation of the free form message.

**(F.R. Page 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**WALGREENS RESPONSE:**

There is no benefit to impeding the momentum driving the adoption of e-prescribing nor the development and implementation of standards for e-prescribing. E-prescribing and EHRs can exist both in an integrative and independent fashion. EHR is very broad and may be implemented in different timeframes and may be driven by different business and clinical needs. E-prescribing is available today and is being used in many clinical settings. As functionality is available, it should be incorporated into the whole continuum of care; but do not postpone implementation of the parts that are available today.

The simultaneous growth and emergence of both systems can occur at various stages independent of each other. There should be no "halt" in eprescribing development. HER is not yet "well defined" and will probably emerge more slowly than eprescribing connectivity.

## II. Provisions of the Proposed Regulation (F.R. Page 6264)

### B. Proposed Definitions (F.R. Page 6265)

- *Dispenser means a person, or other legal entity, licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located, to provide drug products for human use on prescription in the course of professional practice.*
- *Electronic media shall have the same meaning as this term defined for purposes of HIPAA, in 45 CFR 160.103.*
- *E-prescribing means the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network.*
- *Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.*
- *Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use.*
- *Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information or a Part D eligible individual enrolled in a Part D plan.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.**

Walgreens supports the definition of e-prescribing. E-prescribing transactions are defined as "EDI" (Electronic Data Interchange) messages flowing between healthcare providers of prescription or prescription-related information.

Non-EDI Messages (e.g., Faxes or Emails)

Messages that leave or enter the system as an image (e.g. fax or emails) are **not** electronic prescriptions. While it is understood that fax and handwritten prescriptions will continue, these are not e-prescribing EDI transactions.

Walgreens supports the definition of electronic media.

Walgreens recommends the definition of Prescriber be expanded to authorized prescribers of drugs for human or animal use.

### C. Proposed Requirements for Part D Plans (F.R. Page 6265)

**(F.R. Page 6265)**

*We solicit comment on whether Part D plans should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted*
*e-prescribing standards.*

**WALGREENS RESPONSE:**

Standards should be used when transmitting outside of the enterprise and the inter-connection of separate systems.

### E. Proposed Standards (F.R. Page 6265)

*We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction - Filled; Prescription Fill Status Notification Transaction - Not Filled; and Prescription Fill Status Notification Transaction – Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

**WALGREENS RESPONSE:**

Walgreens trading partners using these transactions, especially in the 2006 pilots. Walgreens supports this approach

**(F.R. Page 6265)**

*We propose, in new §423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:*
*• New prescription transaction*
*• Prescription refill request and response transactions*
*• Prescription change request and response transactions*
*• Cancel prescription request and response transactions*
*• The following ancillary messaging and administrative transactions:*
*+Get message transaction*
*+Status response transaction*
*+Error response transaction*
*+Verification transaction*
*+Password change transaction*

**WALGREENS RESPONSE:**

Walgreens supports these transactions being adopted.

**(F.R. Page 6266)**

*We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.*

**WALGREENS RESPONSE: Walgreens agrees with and participated in the formation of NCPDP's response.**

There is a difference between "adopt" and "require". NCPDP prefers CMS adopt these different transactions, but not require them unless the business need or the technology solution is demonstrated. For example, if a provider is connected via the internet/leased line/frame relay, they may not need to support GETMSG mailboxing functions. Why require it when they do not need it?

There is industry experience with STATUS and ERROR. The STATUS and ERROR messages are used today, and these are part of the "real-time" request and response environment of transaction processing. The STATUS and ERROR messages perform transactional functionality; this is different than the housekeeping transactions.

The GETMSG and PASCHG are housekeeping functions. There is adequate industry experience with GETMSG and PASCHG, for those entities needing the functionality.

GETMSG and PASCHG are in a sense internal messages: they flow only between a provider and his mailboxing service (e.g., aggregator), not from one provider to another. Thus, an aggregator may never see GETMSGs from prescribers or an aggregator may never see GETMSGs from pharmacies (depending on the relationship of the technology between the aggregator and the provider). In some instances where a partner does not have a static IP address and "listening capabilities" the GETMSG and PASCHG are being used.

VERIFY is a return receipt function. VERIFY is only used when someone needs it (much like requesting return receipt at USPS; not all mail needs return receipt). The VERIFY message may be used by the end users and sometimes by network partners. There is industry experience using VERIFY, although it should not be a required function as it is not a business function transaction, but rather a special case transaction.

### 2. Eligibility (F.R. Page 6266)

*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

**WALGREENS RESPONSE:**

The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

A clarification. The NCPDP Telecommunication Standard is EDI and was named in HIPAA. It does not adhere to EDIFACT or ASC standards. The NCPDP Telecommunication Standard was named in HIPAA for eligibility between pharmacies and payers. The pharmacy industry will be using the Telecommunication Standard for eligibility checking under MMA, especially in determining coordination of benefits information.

E-prescribing should not be hindered by the length of time that modifications are adopted in HIPAA named transactions.

**(F.R. Page 6267)**
*If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the* ***Federal Register*** *of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

**WALGREENS RESPONSE:**

Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

**(F.R. Page 6267)**
*We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

**WALGREENS RESPONSE:**
Please see response at section "***F. Evolution and Implementation of an Electronic Prescription Drug Program (F.R. page 6261)***".

## IV. Regulatory Impact Analysis (F.R. Page 6268)

*We invite public comment on our expectations for prescriber participation.*

**WALGREENS RESPONSE:**
Please see NCPDP's response at section " ***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**D. Impact on Pharmacies and Other Dispensers (F.R. Page 6271)**
*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**WALGREENS RESPONSE: WALGREENS PARTICIPATED IN THE FORMATION AND AGREES WITH NCPDP'S RESPONSE.**

The NPI is not in use today and the impact on pharmacies of adopting the NPI as an identifier for the electronic Prescriber may not be positive. Prescribers are defined as people and NPIs are to be assigned to places as well as people. The NPPES was not designed with e-prescribing in mind. Some Prescribers do not submit HIPAA transactions and will not have NPIs. The impact could well be negative if the NPI is not piloted and electronic prescriptions are received by pharmacies from places.

It is important that the naming of standards should not negatively impact the electronic prescribing efforts already underway. The process of migrating to new standards and new versions of the standards must be predictable and timely (i.e., sensitive to current industry adoption capabilities)

so as not to negatively impact the movement of the industry as it addresses new business functions and needs.

**E. Impact on Patients (F.R. Page 6271)**

**WALGREENS RESPONSE:**

We agree that the adoption of electronic prescribing will have a net positive impact on patient care with improved outcomes, reduction in errors, and the ability for prescribers to monitor compliance.

**G. Impact on Small Businesses (F.R. Page 6271)**

*Accordingly, we conclude that this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. We welcome comments on this conclusion and additional information on the small business effects of this proposed rule.*

**WALGREENS RESPONSE:**

Participants of NCPDP noted that small businesses, independent pharmacies; small prescriber environments are already using SCRIPT. We are not aware of other studies and agree that more studies will need to be funded to assess and evaluate the overall impact on each of the participant entities. These would be valuable to the industry as a whole.

**H. Effects on States and Federalism Statement (F.R. Page 6272)**

**WALGREENS RESPONSE:**

Please see response at section "***I. Background (F. R. page 6257), 2. State Preemption (F.R. page 6259)".***

**I. Conclusions and Alternatives Considered (F.R. Page 6272)**

*We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

**WALGREENS RESPONSE:**

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard. Please see comments in Section *"G. Electronic Prescription Drug Program (F.R. page 6261)."* Walgreens believes that the NCPDP HCIdea prescriber identifier, which enumerates prescribers and not places, should be piloted as an alternative to the NPI for e-prescribing applications if needed. Careful consideration needs to avoid undue burden on pharmacy systems and prescribers in implementing too complex a message routing format.

**(F.R. Page 6273)**

*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*

**WALGREENS RESPONSE:**

Walgreens supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard, and the Formulary and Benefit Standard.

**PART 423—-VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT**

NCPDP supports the naming of the NCPDP SCRIPT Standard, Medication History transactions, Telecommunication Standard and the Formulary and Benefit Standard.

Conclusion:

Walgreens supports an eprescribing system – including EMR's that allows rapid adoption by all participating entities utilizing proven industry standards such as NCPDP Script. While foundation standards can be initially implemented, attention must be paid to adapting standards in a structured way that is fair to all participants in a practical timeframe without slowing down the adoption of eprescribing and EMR implementation.

Walgreens believes in the preemption in contrary State pharmacy regulations concerning eprescribing. These will only hinder adoption and slow the process of gaining the patient safety and improvement of care benefits EMR's and eprescribing will bring.

Thank-you

Michael J. Simko, R.Ph.
Manager – Pharmacy health Information Technology
Walgreens
200 Wilmot Road
Deerfield, IL 60015
(847) 914-3157

**Submitter :** **Mr. Steve Tucker** **Date: 04/05/2005**

**Organization :** **PacifiCare Heatlh Systems**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0011–P
P.O. Box 8010
Baltimore, MD 21244–1850

American Society of Health-System Pharmacists®
7272 Wisconsin Avenue
Bethesda, Maryland 20814
301-657-3000
Fax: 301-652-8278
www.ashp.org

**Re: CMS-0011-P, Medicare Program; E-Prescribing and the Prescription Drug Program**

To Whom It May Concern:

The American Society of Health-System Pharmacists (ASHP) is pleased to respond to the Centers for Medicare & Medicaid Services' (CMS's) February 4, 2005, proposed rule that would adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). ASHP is the 30,000-member national professional and scientific association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term-care facilities, and other components of health systems. In addition, our Section of Pharmacy Practice Managers has an Advisory Group on Computerized Prescriber Order Entry (CPOE) and Informatics, whose members have provided input for the following comments.

The standards that CMS proposes would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA. Our members have the following concerns about how these standards will be applied. Because of these concerns, particularly the lack of an consideration to pilot test the e-prescribing program, ASHP believes that implementation of final e-prescribing standards should be delayed beyond the proposed January 2006 date.

## I. Background

*Medication History*

A patient's medical history is without a full history of filled and ordered prescriptions. Prescription Drug Plans (PDPs) need to recognize the importance of this complete patient profile, and should provide their network pharmacies with incentives to update their patient profiles for new prescriptions, whether or not they are covered by the PDP.

Currently, Pharmacy Benefit Managers (PBMs) have some limited data on a patient's medication history, but it is not complete. PBM medication history is often only available for those medications that are covered by a patient's plan – a moving and changing set of medications. Information on other medications, not covered by a PDP or PBM that a

patient is taking is essential to making e-prescribing work effectively. A listing of drugs that have been prescribed or claimed across multiple encounter types (inpatient, outpatient, urgent care, emergency care, etc.) and throughout the continuum of care should be required, including over-the-counter, herbal, and nutritional substances. This information is of the utmost value in the context of prescribing and reconciling medications on hospital admission and discharge.

Another concern is that the proposal does not specifically include pharmacists as having access to a patient's medical history." CMS recognizes that there are "disconnects between the prescriber and patient in the medication process," but does not seem to recognize that this disconnect can have serious consequences unless the pharmacist is also involved in the process. Disconnects or fragmentation within the prescribing process leads to fragmented care and adverse drug events. By utilizing electronic systems, the sharing of information in a patient's medical history and the ability to efficiently transfer care between health care providers will allow for improved continuity of care.

*Standards*

Although the currently adopted National Council for Prescription Drug Programs (NCPDP) standards are workable for transmitting billing information, they were not developed to provide clinical care and communicate effectively amongst all providers and across the continuum of care. The process of developing e-prescribing standards should utilize existing medication event/sentinel event root cause analysis data and other medication error reduction initiatives to examine important failures identified during the prescribing process. Many clinical practice quality groups have done important work analyzing the causes of medication errors, and CMS should utilize this information in the process to evolve adopted and additional standards.

*National Provider Identifier (NPI)*

From an e-prescribing perspective, the rapid implementation of an NPI is vital for appropriate follow-up and transfers to downstream care providers. These providers would include pharmacists who provide the medication therapy management program (MTMP) services mandated by the MMA, which CMS called "a cornerstone of the Medicare Prescription Drug Benefit" in the agency's January 28 final regulations for the Part D benefit. The concept of an NPI should be pilot tested early in order to better understand

its ramifications, its interrelationship with the HIPAA-mandated NPI and its acceptance by providers.

## II. Provisions

*Definitions*

The proposed regulation defines "E-prescribing" as "the transmission, using electronic media, of a prescription or prescription-related information, between a prescriber, dispenser, PBM, or health plan, either directly or through an intermediary, including an e-prescribing network." Throughout the proposal, CMS refers to pharmacists as "dispensers." "Dispenser" is defined as "a person or other legal entity licensed, registered, or otherwise permitted by the jurisdiction in which the person practices or the entity is located to provide drug products for human use by prescription in the course of professional practice."

The agency needs to recognize the clinical components of pharmacy work, especially since non-dispensing pharmacists may be significantly involved in providing Part D beneficiaries with the medication therapy management program services required by the MMA. These pharmacists should also be integrated into the e-prescribing program, as they will, by necessity, need to have access to a patient's medication history.

In addition, the definition of "Dispensers" should be modified to clarify that the pharmacist is responsible for the dispensing activity, which includes clinical verification, patient education, etc., as opposed to the pharmacy, which is a business entity.

Although incentives are offered to encourage prescribers to conduct e-prescribing, the proposal contains no requirements for electronic signatures. It is likely that physicians will use office staff to enter a patient's prescription information to obtain the financial incentive. This will result in safety issues. To get maximum clinical benefit, the regulations should specifically require prescriber order entry, including electronic signature by the actual prescriber. It should also require mechanisms to verify that only the prescribers are actually entering the data. The definition of "E-prescribing" should be

rewritten to clarify direct entry of prescriptions by prescribers as opposed to clerical staff and that e-prescribing does not include electronic claims adjudication.

*Pilot Testing*

The CMS proposal states that "the Secretary has tentatively concluded that the proposed standards discussed below are not subject to pilot testing because adequate industry experience with these proposed standards already exists." Despite the National Committee on Vital and Health Statistics (NCVHS) observation that there is adequate industry experience for certain standards, these experiences are industry-driven, and despite some success they may not necessarily be in the best interests of those involved in the medication-use process and, most importantly, the patient.

Although the proposed standards are a good starting point, CMS must also recognize that the agency is setting the stage by stating what is and what is not important to address in the future. By not requiring pilot studies on these proposed standards or the standards developed after reviewing public comments, there will be little evidence on which to base Centers for Medicare & Medicaid Services future standards decisions. The standards being proposed have been used successfully to support reimbursement and manage medication costs and rebate revenues for PBMs. There is no evidence that they have supported better patient care. An example of why such pilot testing is necessary, is the situation in which Cedars-Sinai Medical Center in Los Angeles found itself when it had to suspend implementation of its CPOE system because of problems found while installing the system. According to an article in the *American Journal of Health-System Pharmacy* (Vol. 60, Apr. 1, 2003, pp. 635-42), Rita Shane, the institution's pharmacy director, noted that to be successful, "health systems should conduct extensive testing to identify what changes need to be made before implementing a system and to ensure that staff members clearly understand how to use" new technology.

There are assumptions that the current standards that serve the needs of PBMs and e-prescribing consortiums will provide additional information to support better patient care, but the CMS proposal does not provide a strategy to identify how the results of applying these standards will be measured.

It is vital that pilot projects are developed to represent a variety of practice models, including hospitals with outpatient infusion therapy centers, dialysis centers, oncology clinics, anticoagulation facilities, and dermatology clinics. The pilot projects should also

incorporate all types of prescribing, including IV infusions and Total Parenteral Nutrition.

*Other Provision Issues*

CMS states in the proposal that "the value of e-prescribing in preventing medication errors is that each prescription can be electronically checked at the time of prescribing for dosage, interactions with other medications, and therapeutic duplication." The agency should also include allergy/intolerance checking, as well as validation of patient and correct indication if prescription ordering is linked to a patient problem list.

Another concern is that there are no requirements in the CMS proposed standard for the development of reasonable down-time processes when the electronic systems are not functioning.

**IV. Impact Analysis**

This section of the CMS proposal also recognizes the impact an e-prescribing system will have on pharmacies by reducing the number of telephone calls needed between a pharmacy and a prescriber. It should also include – but does not – the importance of communications between prescribers and pharmacies in order to override prescriptions due to clinical and formulary alerts. This could save a significant number of additional calls.

The CMS proposal references testimony by a representative of SureScripts that 75% of pharmacies in the United States have e-prescribing capability. Elsewhere, CMS states that only 5%-18% of prescribers are using this technology, which means that only the significantly lower percentage of prescriptions are being transmitted electronically. The discrepancy can be explained by the definition CMS proposes for e-prescribing, which would also include electronic prescription adjudication. Because of the SureScripts testimony, CMS assumes that the e-prescribing initiative will have minimal impact on pharmacies. Our members believe that the impact on pharmacies to upgrade systems to support this initiative will be significant.

The proposal states that CMS finds that the "rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay." ASHP believes that the agency has not considered

discharge prescriptions and the need for hospitals to reconcile medications across care settings.

**Conclusion**

Despite the NCVHS endorsement of the NCPDP SCRIPT standard for e-prescribing, ASHP believes that until CMS adopts the RxNorm for the medication entity, and until a better understanding of the prescriber and pharmacy work flow/interface in terms of patient information, clinical alerts and decision support is gained through significant pilot testing in a variety of practice settings, implementation of final e-prescribing standards should be delayed beyond the proposed January 2006 date. Implementing standards that are limited in terms of their sophistication and clinical integration will only lead to a different category of medication errors than are currently experienced. Despite improvements in medication-ordering software tools, the integration with pharmacy systems in all types of outpatient pharmacy settings is limited and untested, still requiring pharmacist transcription, interpretation, and assumption of what the prescriber intended.

The NCPDP standard has been widely tested for billing and dispensing information, which represents only a small portion of the information needed for pharmacists and prescribers to interact in a clinical dialogue regarding a patient's drug therapy. By examining and testing the pharmacist/physician user interface in an integrated inpatient CPOE system or model to get a better understanding of what data elements are necessary to allow for seamless interaction between prescribers and pharmacists. This would provide a more realistic approach and allow for greater success in implementing the e-prescribing program.

As a final point, ASHP cannot overemphasize the necessity for CMS to develop good measures for determining the success of e-prescribing. E-prescribing standards must be designed with these measures in mind, or it may be impossible to determine the net impact of e-prescribing. Deciding not to pilot test the standards does not alter the need to have good measures of success. Possible measures would include system response times, clinical warning override rates, profile request volume by activity (e-prescribing/refill authorization/dispensing) and satisfaction surveys of physicians, pharmacists and patients.

As additional information regarding standards for e-prescribing that should be adopted, we have attached the testimony ASHP presented at the July 28, 2004 public hearing held by the NCVHS's Subcommittee on Standards and Security.

For more than 60 years, ASHP has helped pharmacists and pharmacy technicians who practice in hospitals and health systems improve medication use and enhance patient outcomes. We appreciate the opportunity to present comments on this important patient care issue. Feel free to contact me if you have any questions regarding our comments. I can be reached by telephone at 301-664-8702, or by e-mail at gstein@ashp.org

Sincerely,

Gary C. Stein, Ph.D.
Director, Federal Regulatory Affairs

Attachment

**American Society of Health-System Pharmacists**
**Presentation at the National Committee on Vital and Health Statistics (NCVHS) July 28, 2004, Public Hearing of the Subcommittee on Standards and Security**

Presented by Kevin C. Marvin, R.Ph., M.S.
Senior Project Manager
Fletcher Allen Healthcare
1 Burlington Square
Burlington, VT 05401
802-847-2954
kevin.marvin@vtmednet.org
Chair, Advisory Group on CPOE and Informatics
Section of Pharmacy Practice Managers
American Society of Health-System Pharmacists

My name is Kevin Marvin, and I am a pharmacist currently employed as Senior Project Manager of Information Services at Fletcher Allen Healthcare (FAHC) in Burlington, Vermont. FAHC, in alliance with the University of Vermont College of Medicine, is the only academic medical center in Vermont. Serving Vermont and northeastern New York, FAHC includes 500 licensed beds, 23 sites, and 50 outreach clinics featuring a medical staff of more than 600 physicians

I am also the Chair of the American Society of Health-System Pharmacists (ASHP) Section of Pharmacy Practice Managers Advisory Group on CPOE and Informatics. ASHP is the 30,000-member national professional association that represents pharmacists who practice in hospitals, health maintenance organizations, long-term care facilities, home care agencies, and other components of health care systems. The mission of ASHP is to advance and support the professional practice of pharmacists in hospitals and health systems and serve as their collective voice on issues related to medication use and public health. ASHP has a long history of advocating Congress and federal agencies about the importance of safe and efficient medication use processes. I am pleased to provide you with ASHP's views on the development of ePrescribing standards.

Studies have shown that approximately 2% of all new prescriptions contain 1 or more problems requiring pharmacist intervention prior to dispensing (Rupp 1992 and others). Approximately 0.5% of all new prescriptions contain an error with the potential for harm if it reaches a patient. Based on these numbers, approximately 9.8 million prescription errors with the potential to cause patient harm entered community pharmacies in 2003. Not including hospital errors, $177 billion is spent annually on outpatient medication-related problems in the U.S. (Ernst 2001, Johnson 1995)

Medication orders in hospitals have an even greater rate of errors and, therefore, an even greater need for pharmacist intervention.

Pharmacists serve a unique role in patient care, being responsible for the medication use and drug distribution systems. These responsibilities include complying with the requirements of the FDA, State boards of pharmacy, JCAHO, pharmacy benefit plans and safe practice standards. In addition to dispensing and distribution, a large aspect of the pharmacist responsibility is in the transcription, verification, translation, and communication of medication information between components of the medication use process. ASHP supports efforts to standardize the information pathways in the medication use process that:

- Are developed in an open forum with the involvement of all stakeholders
- Do not hinder the ability to safely and efficiently meet the patient's medication therapy needs
- Are developed in an iterative process with appropriate measures to support continuous improvement to the standards
- Developed in consideration of the need to evolve existing systems to meet the standards

**Identifiers**

There is a need to support universal identifiers of patients. This is especially true apparent when maintaining allergy histories or immunization histories.

Standard methods are also needed to positively verify prescriber identifiers in order to meet FDA and State boards of pharmacy requirements. Other standard identifiers and processes are needed to eliminate the State boards of pharmacy requirements for paper prescriptions for narcotics.

In order to support efficient dose and allergy checking, it is necessary to include patient birth date, height, weight, and certain laboratory results. Minimally, allergy coding should be standardized and stored with the medication profile for retrieval in order to reduce the potential for missed allergy coding.

**Messaging Standards**

Messaging standards of HL7 and NCPDP script have simplified the transmission of medication order and prescription information between components of the medication use process. We support the continued expansion of these standards to meet the ePrescribing and medication use process needs. It is important that the field-level details of these standards match in order to maximize interconnectivity and cross functionality between systems using these standards.

**Coding Standards**

Drug Names

ASHP supports standardization of the use of generic medication names. We support the continued development of RxNorm, which is focused on a generic naming structure. Current drug databases store multiple drug names. Generally, the product-level drug name is determined by the manufacturer and does not follow a specific standard. For example, the following products frequently result in confusion:

- Artificial Tears, Tears Artificial, Saline Sensitive Eyes Formulation, Sodium Chloride OP
- Bupropion XL, Bupropion SR, Bupropion tabs
- Combination product naming using generic vs trade names

Besides drug names, other elements that should be standardized include:

- Dosage Forms -- require standardization to support clinical checking.
- Unit of Measure -- standards will allow automated conversion and dosage checking, i.e. digoxin 125 micrograms = 0.125 milligrams.
- Modifiers -- such as latex, flavor, preservatives, and dyes are needed to support product selection and verification.
- Order Instructions/SIGs:

  Components of the SIG include:

  Frequency
  Route
  Administration site
  Indication
  Medication modifiers (with/without food)
  Conditional frequencies (1 hour before procedure)
  Rates of infusion

The historical Latin standard for SIG coding has been identified as unsafe. Some codes are no longer allowed, but standard alternatives have not been identified. Examples of these include QD, QOD, OS, OD, AS and AD. There is currently a great need and opportunity to standardize a new SIG coding structure.

Order routes of administration need to be standardized to support rule-based clinical checking to reduce false positive warnings for drugs that have multiple routes of administration, such as Gentamycin.

When the above SIG information is not coded in a standard fashion, it is very difficult to accomplish:

- Automated dose checking.
- Medication administration reminders and verification.
- Automated translation of patient instructions to a more understandable format such as another language, $5^{th}$ grade reading level, or audio.

- Historical DUR reporting against free text data.

Free text items reduce the potential to automate downstream components of the medication use process such as medication administration, monitoring, retrospective reporting, and clinical checking. Free text will still be needed to support special needs.

**Other Needs**

EPrescribing standards need to be structured to support medication process workflow and handoffs. This support includes the many communications between physicians, nurses, and pharmacists. Significant telephone time is spent by pharmacists handling refill and third-party payer issues. Technologies are in place to allow patients to electronically request prescription refills from their pharmacy, but no such processes are available to support the requests from pharmacies to the patient's physician and third-party payer pre-authorizations. Automating these processes will significantly enhance workflows in physician offices and pharmacies.

We cannot forget the medication administration component of the ambulatory medication use process. In the hospital environment, significant errors occur in medication administration even though trained professionals are doing the administration. The standardization of prescription terminology throughout the medication use process will support patient needs. Standardized coding of medication information and instructions will allow for good translation of these instructions into language that is better understood by the patient. Consistent labeling and language will support better understanding of patient medication use. Confusing terminology, such as indications and dosing, can be translated in a standard fashion into language the patient understands.

EPrescribing provides opportunities to automate monitoring of the medication administration side of ambulatory medication use process, including:

- Monitoring of refill activity.
- Monitoring whether new written prescriptions are filled.
- Providing prescription fill and refill information to prescribers.

Standardized administration instructions can be interfaced to:

- Electronic reminders built into dispensing packages.
- Voice reminders (take on empty stomach, medication reason, dose due).

**Need for Content Standards for all Relevant Fields in Medications and Orders**

The conversion of a prescription in ePrescribing to a pharmacy product is a complex process. It is common in the current hospital world for a Computerized Prescriber Order Entry (CPOE) system to be implemented that results in the electronic order being printed to paper in the pharmacy and transcribed back into a pharmacy computer system for dispensing. Hospitals with proprietary integrated CPOE/pharmacy systems are the only

ones that have implemented CPOE without some type of manual process to convert the physician order to a pharmacy product. With hospital CPOE systems, physician orders can be pre-built with the pharmacy product pre-selected from the hospital's formulary. This cannot occur with ePrescribing in an open ambulatory environment, where the product selection is determined by a combination of the patient's pharmacy insurance benefit, patient choice, and the inventory of the pharmacy filling the prescription. A typical inpatient pharmacy carries approximately 2500-3000 products in stock. The total number of NDC products available has been mentioned by other testifiers to be approximately 80,000, and significantly more if OTC products are included.

Example of a matching process issue:

- Selection of the right combination of strengths for the dose
  Example 12.5mg Warfarin
  a) 10mg + 2.5mg
  b) (2 x 5mg) + 2.5mg
  c) 2 ½ x 5mg
  d) 5 x 2.5mg

If ePrescribing standards do not consider the translation of medication entity to product detail we will still have an error-prone transcription process. We need to develop standards that avoid this unacceptable solution.

**Prescription Order Data Integrity and Control**

Standards are needed to support the integrity of the original written prescription. The systems should assure that pharmacists are not modifying the intent of the prescription and are selecting the appropriate product to match the medication entity prescribed. Therefore, the data elements carried in the original ePrescription should carry forward to the final prescription filled. Additional data elements will be coded based on the product selected. This is necessary to:

- Support the rule-based clinical checks that work the same for Physicians and Pharmacists.
- Support rule-based product selection.
- Support better physician-pharmacist-patient communication.
- Reduce transcription and translation errors by allowing the patient to be part of the verification chain by seeing the prescription as it was originally written without transcription.

Standards need to provide a hierarchical framework for medication coding from the drug entity level down to the product level (NDC). It is likely that manual transcription will continue to occur until this hierarchical structure is developed.

As prescription information moves through the medication use process, it should be added to but not modified or deleted. This is supported best via hierarchical data structures. Standards are needed to clearly define the source and owners of each data element in an order or prescription. This is necessary to control data integrity. In some cases the ownership can be shared, but the rules need to be clearly defined.

**Standards to Support Workflow**

Standardized methods are needed to support and enhance communication processes. The system needs to support the communication of decision rationale downstream in the medication use process.

Example: Support the communication of warnings to override rationale by the physician to avoid follow up communication by the pharmacist. Such overrides can occur when the physician selects non-covered or higher cost medications or overrides clinical warnings.

Some expansion of the messaging standard will be needed to better support the handoff of prescriptions from the physician's office to the pharmacy. In addition to prescription information, the passing of medical benefit plan information to the pharmacy will support faster processing of prescriptions by the pharmacy. Also, it will be best if the patient's HIPAA release for the pharmacy is received prior to or during this handoff. Without proper patient approvals, the pharmacy will not be able to access the patient's global medication history and fill the prescription until the patient arrives. This will create unneeded delays for the patient.

In addition, the ePrescribing system should support upstream communication in the medication use process. Such upstream communication includes requests for refill authorization or pharmacist interventions to clarify dosing, routes, etc.

**Patient Empowerment**

EPrescribing standards need to support patient empowerment. Patients need to be able to select the pharmacy and payment method, as well as influence product selection within the prescriber's intent. Patients also need the ability to review their consolidated medication history information. Standards need to support these goals, as well as provide a mechanism for the patient to verify that the medication received matches the medication ordered.

**Standards to Support Measurement**

The development of ePrescribing standards is a continuous improvement process that will occur through iterations of design, change, and measurement. Methodologies are needed to measure the safety and efficiency of the system and to provide the evidence to support

continuous improvement of the processes and standards. Such measurement standards should include:

- Time stamps to address response times of automated systems and process steps.
- Methods to document and measure interventions that will support the identification of improvements in:
  - Safety
  - Efficiency
  - Financial Performance

Mechanisms are needed to monitor the measures and, as appropriate, to adjust systems, processes, and standards for improvement.

**Recent Directions from JCAHO**

On July 20, 2004, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced a new 2005 National Patient Safety Goal:

> Goal: Accurately and completely reconcile medications across the continuum of care.
>
> - During 2005, for full implementation by January 2006, develop a process for obtaining and documenting a complete list of the patient's current medications upon the patient's admission to the organization and with the involvement of the patient. This process includes a comparison of the medications the organization provides to those on the list.
> - A complete list of the patient's medications is communicated to the next provider of service when it refers or transfers a patient to another setting, service, practitioner or level of care within or outside the organization.

This direction from JCAHO will significantly increase the interest in the ePrescribing effort within health systems. It will also include the need to support profile lists of OTC medications, dietary supplements, drug samples, take home medications, and possibly medications administered in clinics and hospitals. Note the requirement for full implementation by January 2006.

It is important to recognize that the ePrescribing standards, although starting as electronic prescribing, will evolve to include all medications. Since these medications will eventually all be included on the same medication profile, they should ultimately share the same standard.

It is possible that the electronic profile functionality of ePrescribing will support this need to reconcile prescriptions. Additional medication profile functions may be needed to complete this support. These functions include:

- Patient access to the profile for verification.
- Documentation that a profile review has occurred by pharmacist, nurse, physician or patient.
- Addition of medications to the profile as documentation only.

**Pharmacist Verification of Orders**

JCAHO and State boards of pharmacy require that pharmacists review medication orders prior to the medication being dispensed to the patient except in emergencies. In order to support this order verification, pharmacists need complete access to a patient's medication profile, allergy information, problem or diagnosis list, height/weight information, and other applicable laboratory results and clinical data. This requirement for pharmacist verification recognizes that the electronic rule-based clinical checks are not complete and do not support other pharmacist functions, including:

Patient monitoring
Patient education
Local and regional practice differences
Identification of programming or system setup errors

**Conclusion**

Finally, I would like to emphasize that the development of ePrescribing standards will be an ongoing effort, with iterations of improvement. Pharmacists are important members of the healthcare team to assure that the components of the medication use process meet the requirements of legal and regulatory compliance, payers, and -- most importantly – the best care of patients.

Again I thank the subcommittee for providing this opportunity to present the health system pharmacist's perspective with regards to the development of ePrescribing standards.

ASHP remains available to provide input as these recommendations are developed.

**Submitter :** **Dr. Gary Stein** **Date: 04/05/2005**

**Organization :** **American Society of Health-System Pharmacists**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-43-Attach-1.DOC

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
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We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Mr. Robert Tennant** **Date: 04/05/2005**

**Organization :** **Medical Group Management Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

**Issues**

Background

See Attachment

Regulatory Impact Analysis

See attachment

Collection of Information Requirements

See attachment

Provisions of the Proposed Regulation

See attachment

CMS-0011-P-44-Attach-1.DOC

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 5, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P
P.O. Box 8014,
Baltimore, MD 21244-8014

**Re: Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule**

Dear Administrator McClellan:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the proposed rule on e-prescribing. MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

## General Comments

As the federal government and the health care industry move toward adoption of standards for electronic prescribing, the following issues should be considered:

- E-prescribing Standards Should be Flexible and Scalable – From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. The final standards must be both flexible and scalable to encourage adoption by both small and large health care organizations and low- to high-volume prescribing physician specialties. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency and integration with existing practice management software and electronic medical record systems when making an investment.

- E-prescribing Standards Should not Impose Undue Burdens on Providers – In these challenging economic times, with decreasing reimbursement and increasing practice expenses, it is critical that the Centers for Medicare and Medicaid Services (CMS) craft a final rule that does impose undue financial burdens on physician practices. Furthermore, e-prescribing systems should be designed in such a way that clinicians are able to utilize this technology in a time-efficient manner. Clinicians may be discouraged from adopting the technology if it takes them significantly more time to write a prescription electronically than on paper.

- Ensure System Interoperability – In order for an electronic prescribing system in a medical practice to communicate effectively and securely and share patient data with

HEADQUARTERS
104 Inverness Terrace East
Englewood, CO 80112-5306
phone: 303.799.1111
fax: 303.643.4439

GOVERNMENT AFFAIRS
1717 Pennsylvania Avenue
North West, Suite 600
Washington, DC 20006
phone: 202.293.3450
fax: 202.293.2787

www.mgma.com

other medical practices, hospitals and pharmacies, they all must speak the same "language." E-health standards developed by either the federal government or industry must have the ability to be utilized by multiple stakeholders using a myriad of computer systems. At the same time, "interoperability" should also include the ability for an electronic prescribing system to seamlessly interact with other clinical and administrative systems in the practice.

- Promote the Security and Privacy of Patient Data – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). E-prescribing must maintain these HIPAA standards as part of its core operating features.

- Establish a Quantifiable Return on Investment – For many group practices, the economics of investing in e-prescribing and other health information technology is simply not evident. In an environment of significant scheduled Medicare reimbursement cuts, sharply rising malpractice premiums and ever-increasing practice expenses, many practices are concerned that moving to an electronic information system will not be financially beneficial. MGMA recommends that CMS establish a quantifiable return on investment through survey research and a comprehensive cost/benefit analysis for all sizes of physician practices.

- Incentives for Providers – While medical practices typically absorb the cost of purchasing the health information technology necessary for electronic prescribing many of the benefits accrue to others in the system. MGMA believes there should be a "realigning" of these incentives by promoting appropriate public and commercial reimbursement programs. MGMA has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Additionally, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could also be a stimulus.

- Technology Savings Accounts – The federal government should also explore innovative methods of assisting physician practices to acquire health information technology such as electronic prescribing. Technology Savings Accounts (TSAs) would provide a reduced level of taxation for funds designated for practice health information technology. A TSA would be a special account owned by a group practice where contributions to the account pay for current and future qualified health information technology expenses including electronic prescribing software and hardware. A TSA savings product offers a different way for group practices to pay for their health information technology expenses. TSAs could enable group practices to pay for current expenses and save for future qualified health information technology expenses on a tax-free basis. Unspent account balances would accumulate and accrue interest.

- Stark Regulation Safe Harbor – There are clear legal barriers to the adoption of health technology solutions in medical groups. Anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices. MGMA has advocated for government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation. We congratulate the CMS recent important step in this direction through its creation of a health technology safe harbor in the physician self-referral phase II interim final rule (CMS-1810-IFC; 59 Fed Reg 16054).

- Consultation with the Physician Practice Community – Physician practices must play an integral role the development and deployment of any standardized e-prescribing system. Since the vast majority of all health care is delivered in medical practices, the success or failure of these initiatives will depend heavily upon physician acceptance of this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Patient and Provider Outreach – The successful adoption of e-prescribing will depend, in part, on the ability of the federal government and the industry to encourage both providers and pharmacies to understand and support the system. It is imperative that these two critical stakeholders are well educated as to the systems' capabilities as well as its security and privacy components. In addition, MGMA recommends that CMS work with the appropriate provider and consumer associations as well as the popular media to deliver a consistent message to patients on this important change in the health care system.

- Work with the industry to expand this regulation beyond Medicare Part D – This regulation is expected to enhance patient safety and efficiency for the Medicare Part D program. CMS should expand the use of this standard beyond Medicare and MGMA is hopeful that a successful implementation of this regulation will trigger adoption of these standards by the private sector. MGMA encourages CMS to facilitate this expansion by working with the private sector to exchange data and experiences as well as develop educational materials that will assist stakeholders move forward with e-prescribing.

- Learn from the HIPAA Experience – The protracted nature of HIPAA Transactions and Code Sets implementation process suggests that the federal government's e-health regulatory process must be modified. MGMA calls on the government to stagger implementation dates, thus providing health plans and clearinghouses time to upgrade and test systems before provider implementation takes effect. While piloting is not needed to establish the applicability of the core function standards, piloting of the entire e-prescribing standard should be completed prior to full national implementation in order to identify and correct problems.

**Specific Comments on the Notice of Proposed Rule Making**

Issue: **State Preemption (70 Federal Register No. 23 Feb. 4, 2005 page 6258)**

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

Response:

MGMA believes that the proposed rule adopts a very narrow interpretation of federal preemption. The rule appears to limit preemption to only those Part D beneficiaries enrolled at the time the prescription is issued, rather than all Medicare beneficiaries. We also have a concern that Medicare beneficiaries may receive drug coverage from multiple sources. Yet, the rule seems to

limit preemption to only those prescriptions actually covered by Part D. MGMA recommends that CMS adopt an interpretation providing that federal law broadly preempts any state laws that are contrary to or that stand as an obstacle to the objectives of the federal government in creating the e-prescribing standards. We believe that this interpretation is consistent with the settled view of preemption and statutory language. MGMA also suggests to CMS that the preemption standard apply to any prescription issued to any beneficiary eligible for Part D coverage.

Issue: **Current E-prescribing Environment (70 Fed Reg 6260)**

*The use of e-prescribing shows promise for improving Medicare operations by creating efficiencies in the administration of the Part D drug benefit, by decreasing costs in facilitating patient eligibility checks, promoting generic drug use, and creating timely interface with formularies. This also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.*

Response:
MGMA believes that e-prescribing will help to deliver relevant patient information and clinical knowledge to the clinician and this will reduce the likelihood of a faulty prescription. In addition, e-prescribing holds the promise of improved administrative efficiencies. Presenting all relevant information to the clinician at the time of prescribing may help streamline the entire prescribing process. Relying solely on downstream inspection to manage quality is inefficient because of the extra work required. By some accounts, the nation's three billion prescriptions generate approximately 150 million clarification phone calls every year. This means that roughly five percent of prescriptions are somehow incompletely specified or unclear, and need to be reworked.

Early experience supports the view that electronic prescribing – by shifting the error-inspection process to the point of prescribing – reduces callback volume and improves efficiency. In fact, most clinics that successfully deploy electronic prescribing applications note a dramatic decrease in prescription clarification calls. Moreover, those callbacks that still occur can usually be processed more efficiently because of the streamlined message-handling capabilities that often come with electronic prescribing, coupled with elimination of the need to pull (and re-file) paper charts every time a pharmacist or patient calls with a question or concern about a prescription. This reduction in chart pulls is one of the unheralded beneficial side effects of electronic prescribing and has major cost-savings implications, particularly for larger practices. Even in small practices, however, there is still significant time lost looking for charts that have not been filed and are in multiple locations around the office, waiting for various processes to be completed.

Issue: **Evolution of Standards (70 Fed Reg 6261)**

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

Response:

MGMA supports the creation of e-prescribing standards as needed by the private sector through ANSI accredited standards developing organizations, with federal government participation in the standards development process. We urge that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to that experienced with the HIPAA

Transactions and Code Set standards. In addition, MGMA recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and any interested party should be eligible to submit proposals for additions and modifications. A responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain these vocabularies.

Issue: **Criteria to Assess "Adequate Industry Experience" (70 Fed Reg 6261)**

*We propose to use the following criteria to assess adequate industry experience (with transaction standards), based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:*

- *The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

- *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

- *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

Response:

MGMA agrees with this approach to determine if a standard is deemed to have had "adequate industry experience." We would like to emphasize the importance of the final bullet, that the standard be recognized by key industry stakeholders, as this is critical to ensure that the standard has been used in clinical settings and found to be acceptable. In particular, we encourage CMS to continue its outreach to the provider community to ensure that any futures, standards take into account the requirement of clinicians.

Issue: **Drug orders for fill status notification (70 Fed Reg 6262)**

*NCVHS Standards Recommendations – HHS Should :include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. Standard in the NPRM: No.*

Response:

MGMA is disappointed that CMS decided not to include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. This standard has the potential of significantly improving the health of Medicare beneficiaries. With some industry sources estimating that up to 40 percent of written prescriptions are never filled by the patient, it is clear that many patient conditions are not easily monitored by physicians.

Failure to refill medications at a pharmacy or renew at the clinician's office in a timely fashion can and does lead to adverse events due to exacerbations of the condition. This is a significant

problem particularly for persons who have difficulty affording their prescriptions. Renewing prescriptions in a timely fashion may not be a high priority, especially for drugs that treat relatively asymptomatic chronic conditions. Lack of patient compliance with prescribed medications can also lead to similar adverse events. With electronic prescribing systems leading to better tracking of a patient's drug regimen, it is possible to know when renewals of regularly scheduled medications are likely to come due, assuming proper patient compliance. Systems can send out reminders to patients and clinicians, advising of an upcoming renewal or refill time and even offering one-click renewal transactions. These reminders should have a positive impact on actual compliance.

It would be easy for elderly Medicare beneficiaries, who may be taking multiple prescription drugs, to miss filling an important prescription. Thus, prescription fill status could be an important device allowing clinicians to better monitor chronic care illness, potentially lowering overall health costs by preventing hospitalizations due to improper drug usage. In addition, fill status would potentially be an important patient safety, patient satisfaction and quality measurement. We are hopeful CMS will consider including this function in later standards.

Issue: **Version Control (70 Fed Reg 6267)**

*If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the Federal Register of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

Response:

MGMA recommends that HHS (i) adopt minimal version levels of the standards; (ii) depend on existing standards developing organization (SDO) enhancement processes for newer versions; and (iii) permits health care organizations to use newer versions provided there is backward compatibility. MGMA recommends that the National Committee on Vital Health Statistics (NCVHS) hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such updates to HHS. If NCVHS considers the change to be substantive, as described on 70 Fed Reg 6267 above, HHS would issue a NPRM within 90 days. If the change is deemed not to be substantive, it would waive notice and comment.

MGMA is concerned about any possible divergence between a HIPAA standard transactions and the same e-prescribing transaction, such as the ASC X12N 270/271 eligibility inquiry. MGMA recommends that procedures be designed to permit the changing needs of HIPAA and e-prescribing to be met but that such modifications to standards do not result in multiple standards. MGMA also recommends consideration of implementation phases rather than requiring all transactions by a single date.

Issue: **National Provider Identifier (70 Fed Reg 6263)**

*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

Response:
MGMA is a strong supporter of administrative simplification and believes that the national provider identifier (NPI) is an important step in streamlining health care transactions. The NPI should be the primary identifier for all prescribers and dispensers utilizing e-prescribing. MGMA recommends that current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

In addition, while MGMA recommends that the required date for use of the NPI in transactions in this NPRM not be sooner than the required date for use of the NPI in HIPAA transactions, we strongly urge CMS to move forward with the NPI enumeration process. E-prescribing will be greatly facilitated with a standard provider identifier. We recommend that CMS work with providers and other stakeholders to develop an NPI implementation plan that results in rapid and successful adoption of this important new standard.

Issue: **Formulary and Medications Standards (70 Fed Reg 6263)**

*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*

Response:

In order to facilitate a successful implementation, MGMA recommends that the formulary, benefit and medication history messaging standards should be thoroughly pilot-tested prior to the release of a final rule. Vendors should be factored into the regulations and encouraged to bring products to market that assist physicians in complying with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered, as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide the tools necessary to comply with the electronic prescribing program. Strong government leadership will

be critical to rapid and seamless conversion to the new standard.

MGMA urges that HHS make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of HIPAA. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-agency differences from across the federal government in the Addendum to the Electronic Transactions and Code Sets rule (citation). The additional time to resolve these differences left inadequate time for the various vendors to work with their provider and payer customers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long and not conducive to industry usage.

Issue: **Medication History (70 Fed Reg 6263)**

*We propose the following critical characteristics for medication history standards:*

- *The standards are accredited by an ANSI-accredited standards development organization.*
- *The standards permit interface with multiple product, router, and POC vendors.*
- *The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*
- *The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.*

Response:

MGMA recommends private sector development and maintenance of standards and modifications and enhancements to standards not be hindered by extensive rule-making processes. We are concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the HIPAA Privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

MGMA is also concerned that the current models for retrieving prescription and medical history is daunting. For example, patients often utilize multiple pharmacies—often making the prescription record at any one site incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

Issue: **Proposed Standards (70 Fed Reg 6264)**

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for*

*formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

- *The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

- *The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

- *The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

Response:

MGMA agrees with moving forward with these "foundation" standards. It is clear that the industry has already adopted these standards and that they meet the basic needs of the industry. However, MGMA encourages moving to new standard versions as soon as practical, in particular, moving to the new versions of the ASC X12N 270/271 and 278. MGMA also agrees that these foundation standards do not need to be piloted to determine their applicability to the e-prescribing regulation. However, as noted above, we encourage CMS to initiate a comprehensive pilot of the entire standard prior to implementation.

For future additions to the standard, MGMA recommends pilot projects in order to prove the standards not named as foundation standards will work in multiple provider and pharmacy environments. As well, pilot projects should address workflow issues and establish the business rules in order not to impose undue burden on physicians and pharmacies. MGMA recommends that demonstration pilots show achievable financial models for appropriately funding the acquisition of technology, training and support for electronic prescribing in various clinical settings. Pilot projects may also be required for any standard already demonstrated but being proposed for use in new circumstances.

Issue: **Strategy for Phasing in Implementation of an Electronic Prescription Drug Program (70 Fed Reg 6264)**

*In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking.*

Response:

MGMA agrees with this phased in approach to the e-prescribing standards. It is important to have the foundation standards adopted quickly by the industry to ensure that the benefits of e-prescribing are achieved in a timely manner. It is also important to move forward with the additional standards with all deliberate speed, with the caveat that these standards be properly vetted through the appropriate standards organizations and piloted when there is insufficient industry experience. MGMA encourages CMS to institute a comprehensive industry outreach program, focused on the provider community. Each release of a new e-prescribing standard should be prefaced with an educational program to explain the new standard and how it should best be implemented.

Issue: **Eligibility (70 Fed Reg 6266)**

*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors…*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

Response:

For eligibility inquiry and response, MGMA supports the ASC X12N 270/271 for the patient eligibility and benefits inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA. However, as much as this transaction has the capability of significant return on investment by reducing the cost for both medical practices and health plans to verify patient eligibility, in reality, much of the value of this transaction has not been realized. Medical practices report that health plans are simply responding with a "yes" or "no" when queried. While this is permitted under HIPAA, this minimum level of response necessitates the practice use the telephone to ascertain other eligibility information from the health plan – thus incurring significant costs to their organization and for the health plan.

We are hopeful that a recent industry initiative may assist in providing additional electronic eligibility and benefits information to medical practices. MGMA is working with Council for Affordable Quality Healthcare (CAQH) to improve the quality of 271 eligibility responses from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. The CAQH is seeking to define operating rules that health plans will voluntarily adopt, providing information as to whether the patient is covered and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. MGMA recommends that CMS consider modifying the 270/271 to include these operating rules as required data elements in future versions of the standard.

Issue: **Coordinate Update Process when e-prescribing and HIPAA Standards are the Same (70 Fed Reg 6267)**

*We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 16 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

Response:

MGMA recommends that CMS not approach standards that fall within the purview of both e-prescribing and HIPAA differently. CMS should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

Issue: **Regulatory Impact Analysis (70 Fed Reg 6268)**

*We invite public comment on our expectations for prescriber participation.*

Response:

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2011. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40 percent less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of e-prescribing's promise of improved efficiency, patient safety and health care quality. MGMA believes that e-prescribing offers significant financial and other benefit potential to providers. However, this observation may not appear compelling to many providers in the financial environment between now and 2011. MGMA recommends that CMS fund the development, analysis and educational documentation making the financial case for providers to implement health information technology.

Issue: **Standards Development Approach (70 Fed Reg 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

Response:

MGMA believes interoperability with many clinical terms is very important. For example, some terms may be used differently in a hospital setting than an ambulatory environment. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality and efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process. Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

Issue: **Regulatory Impact (70 Fed Reg 6269)**

*We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.*

**Provider Savings, especially solo and small groups (70 Fed Reg 6270)**

*We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.*

**Applying the ROI of larger practices to smaller practices (70 Fed Reg 6270)**

*These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual or potential savings, particularly in solo and small group practices.*

Response:

Without conducting a wide-ranging survey, MGMA is not in position to provide a detailed impact analysis of these proposed regulations on different types of participants. It is critical, however, that CMS develop a comprehensive and accurate report of the full costs and savings in order to fully understand the impact that this regulation will have on the industry. In particular, MGMA encourages CMS to conduct this important analysis as soon as possible as the results will not only help to guide the policy development process but may also help to facilitate the provider community's acceptance of this technology. It appears as though only a small percentage of practices are currently utilizing e-prescribing, though a significant number are expecting to move to this technology over the next 24 months. MGMA, however, is positioned and willing to develop and analyze surveys for CMS, as well as educational documentation, analysis and financial models, and pilot and testing projects.

Issue: **Application of e-prescribing rules to Part B drugs** (70 Fed Reg 6273)

*Proposed definition 42 CFR 423.159: "Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs…"*

Comment:

The expansion of the Part D benefit to drugs currently covered by the Medicare system remains a complex aspect of the implementation of the Part D program and the Electronic Prescription Drug Program. Many industry groups, including MGMA, assert that this nexus will result in numerous providers who did not consider themselves to be directly affected by Part D to be swept into the program's requirements, including the e-prescribing obligations.

MGMA seeks clarification, how, if at all, providers will be required to incorporate e-prescribing technologies if ordering drugs currently paid under the Part B program or acquired through the proposed Competitive Acquisition Program (CAP). The proposed rule for the CAP (CMS-1325-P; 70 Fed Reg 10746), acknowledges that drugs dispensed by venders would require a physician's order. This order would include a request for the complete treatment of the patient (multiple doses) and includes the (a) date of order; (b) beneficiary name; (c) physician identifying information, name, practice location, group practice information (if applicable) and Medicare enrollment number; (d) drug name; (e) strength; (f) quantity ordered; (g) dose; (h) frequency/instructions; (i) anticipated date of administration; (j) beneficiary Medicare information/health insurance number; (k) Medicare information; (l) shipping address; and (m) additional patient information including date of birth, allergies, height, weight, diagnosis codes, etc. We recommend that CMS ensure that all of these requirements will be able to be performed with the proposed NCPDP SCRIPT standard. It would be very burdensome if providers are required to submit some of the information through an e-prescribing system and other required data sets through a separate system, either electronic- or paper-based.

Furthermore, the proposed CAP would assign individual Medicare prescription numbers to dispensed drugs used in claims adjudication and payment. CMS should ensure that the NCPDP SCRIPT standard has the ability capture this specific number for Medicare processing.

Lastly, it remains unclear from the proposed CAP regulation, if CAP vendors would be required to use the standards established under the Electronic Prescription Drug Program. It appears that this proposed rule intends to require prescribing physicians and pharmacies/entities of any drug payable under the Medicare program to adhere to the requirements of the Electronic Prescription Drug Program. However, this additional future obligation is not made clear in the CAP regulation, or in the "CAP Vendor Application and Bid Form" or accompanying "CAP Drug Vendor Application Guide" (OMB Approval Pending No. 0938).

MGMA appreciates your consideration of these comments. If you have any questions, please contact Robert Tennant in the MGMA Government Affairs Department at (202) 293-3450.

Sincerely,

William F. Jessee, MD, FACMPE
President and CEO

**Submitter :** **Mr. Steve Tucker** **Date: 04/05/2005**

**Organization :** **PacifiCare Health Systems**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attached.

CMS-0011-P-45-Attach-1.DOC

PacifiCare®

April 5, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P,
P.O. Box 8014,
Baltimore, MD 21244-8014.

RE: CMS-0011-P

Dear Sir or Madam:

On behalf of PacifiCare Health Systems, Inc. (PHS), I am responding with comments on the Notice of Proposed Rule Making for the Medicare electronic prescribing program.

PacifiCare is one of the nation's largest consumer and health services organizations, offering groups and individuals, including Medicare beneficiaries, a variety of consumer-driven health care and insurance products. PacifiCare currently serves some 700,000 Medicare beneficiaries enrolled on our Medicare Advantage plan – Secure Horizons – in eight western states. We have been participating in the Medicare risk program since its inception in the mid-1980s. Our wholly owned subsidiary, Prescription Solutions, provides comprehensive pharmacy benefit management services to our Medicare and commercial members as well as members of other external clients, serving over five million lives in total.

We greatly appreciate the opportunity to review these documents and provide commentary. We look forward to working with the Agency to implement the MMA.

If you have any questions, please contact me at (714) 226-3697.

Sincerely,

Steve Tucker,
Vice President
Regulatory Affairs

SMT:jlh

Attachment: Detailed Comments on CMS 0011-P

# Medicare Part D Commentary

CMS-0011-P

Medicare Program
E-Prescribing and the Prescription Drug Program

Submitted by
PacifiCare Health Systems
and Prescription Solutions

**OVERVIEW:**

PacifiCare appreciates the ability to provide comment on the proposed rule for the Medicare Program; E-Prescribing and the Prescription Drug Program published in the Federal Register on February 4th, 2005.

PacifiCare commends the Centers for Medicare & Medicaid Services (CMS) for actively developing and promoting electronic prescribing. We agree that electronic health record frontier holds the promise of reducing medical errors and vastly improving patient safety. We also recognize the work of the National Committee on Vital Health Statistics (NCVHS) and believe the Committee's initial recommendations to the Secretary helped to provide a framework for the e-prescribing environment.

The statute calls for the establishment of pilot programs beginning in 2006 to test the emerging electronic prescribing standards and we strongly support this requirement. PacifiCare was an early supporter of e-prescribing understanding the fundamental and unique benefits that this technology offers. We also acknowledge that for industry wide adoption to be successful, the infrastructure must be appropriately planned and implemented according to the real world environment. Finding the right balance for accelerated adoption of this new platform and ensuring success, in light of enormous modifications taking place with the new Part D benefit, will be a challenge and will require flexibility by CMS while plan sponsors develop each of the necessary component programs for successful implementation of the drug benefit in 2006. We believe that the pilots recommended by the Medicare Modernization Act (MMA) will provide the testing phase necessary to validate assumptions and negate the possible introduction of unanticipated problems. Therefore, it will be critical to allow the pilot programs to be completed prior to introduction of any broad e-prescribing capability. As with any new innovation, especially one steeped in an information technology function, intended solutions need to be confirmed prior to finalizing protocols.

**I Background**

**"BACKGROUND"**

**Compliance Date**

The Secretary proposes January 1, 2006 as the compliance date for the proposed foundation standards. We believe that the proposed timeline for the implementation of any e-prescribing standard by January 1, 2006 is operationally unfeasible and national implementation should be delayed.

After attending CMS open door forums on the MMA drug benefit and asking direct questions of CMS staff regarding the proposed e-prescribing compliance date, PacifiCare understands and has relied on the representation that the compliance date would only apply to those companies having e-prescribing programs in place on or after that date. It is also our understanding that there is no requirement that a company create a fully operational e-prescribing capability for the January 1, 2006 date. Indeed, the anticipated pilot programs intended to provide the experience and detail necessary to create the e-prescribing final standards will not have begun until on or after that date.

Additionally, health plans considering Part D participation have begun tasks associated with the annual contracting process. These activities reflect the requirements contained in the final Title I & II regulations and components integral to the Medicare Advantage (MA) and Prescription Drug Plan (PDP) application process. The timeline set forth by CMS for completion of the MA or PDP application requires that plans submit finalized participating pharmacy networks no later than July 15, 2005. In order to meet these strict deadlines, PacifiCare has initiated the overall contracting of the provider networks essential in meeting the Part D *Standards for Convenient Access* requirements.

The extremely aggressive implementation timeline proposed for e-prescribing foundation standards provides insufficient time necessary for encompassing the operational tasks associated with communicating contractual requirements to downstream providers. The activities involved with provider network contracting are resource intensive and time consuming, especially with the advent of a new product offering combined with the size of the regional pharmacy networks. Given that the e-prescribing regulations will not be finalized with adequate time to be incorporated into the current contracting cycle, we urge CMS to include the final provisions in the pilot testing phase.

**Initial Standards Versus Final Standards**

While the Secretary is permitted under the statute to pre-empt the pilot testing of components if sufficient real-world experience exists, we believe that by and large, e-prescribing is still in the infant stage and that all proposed standards should be tested in the pilot programs prior to nationwide roll-out. We have noted the observations made by the Secretary for the accelerated advancement of this technology as a step towards embracing a full electronic health record.

However, moving too quickly with mandatory standards may compromise overall prescriber participation and diminish the benefits associated with this endeavor.

The true e-prescribing environment is a recent phenomena only being credibly established over the last two to three years. The majority of e-prescribing studies have been conducted under optimal test site conditions and supported with resources to ensure success. Given that less than 10% of doctors currently use electronic prescribing, coupled with the multifaceted issues that impact provider use of new information technologies in the office setting, it is critical that e-prescribing be tested and validated prior to wide-spread implementation.

**State Preemption**

PacifiCare believes that adoption of unified e-prescribing standards through appropriate and full federal preemption of state laws is essential to overall success of e-prescribing in the health care industry. The Federal government and the States have distinct roles in relation to e-prescribing. While dispensers are ultimately responsible for ensuring the validity and authenticity of prescriptions under state statutes, prescribing requirements are controlled by state boards of pharmacy and the U.S. Department of Justice Drug Enforcement Administration (DEA).

There are state-to-state variations relating to prescribing requirements and the DEA currently requires Schedule II controlled substances to be authorized by the prescriber with a handwritten signature. Additionally, the NPRM notes that "The DEA has not yet made a ruling regarding the requirements for the electronic transmission of prescriptions for controlled substances." To reduce barriers and increase adoption of this new technology, we urge CMS to invoke preemption authority as afforded in the MMA.

**Anti-kickback Statute Safe Harbor and Stark Exception Section**

Numerous studies have identified economic barriers that retard physician adoption of e-prescribing. Without the support of these resources prescribers will not be incentivized to entertain this new tool, particularly as their organizations embrace various issues presented with the new Part D benefit. The protections afforded by the anti-kickback statute safe harbor are essential to the success of the e-prescribing program and we suggest that that the overall e-prescribing program be delayed, if the new exception for e-prescribing is not timely aligned with the e-prescribing initiative.

**Evolution and Implementation of an Electronic Prescription Program**

We believe that further articulation of these criteria is necessary and PacifiCare recommends that CMS clarify the subparts of the proposed definition for determining "adequate industry experience".

> • *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

PacifiCare recommends that CMS provide the basis for concluding that the "standard has been generally implemented by entities to which the final standard will be applied" including the sampling methodology, survey instruments, and the result authentication mechanism used to reach consensus of the assumptions used in this criterion.

> • *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

Pacificare suggests that CMS identify the methodology used to include entities as key industry stakeholders and the oversight process used to ensure that potential conflicts of interest do not pervade these decision making proceedings.

**Provider and Dispenser Identifiers**

The Secretary of Health and Human Services is required to adopt a national standard identifier (NPI) for health care providers under the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPPA) of 1996. Although providers can begin to apply for an NPI in May 2005, most covered entities are not required to begin using the NPI until May 2007. Currently, physicians are identified by their DEA number. However, physicians who do not prescribe controlled substances may not hold a DEA number. Although the MMA does not expressly require the use of unique identifiers for prescribers or dispensers in e-prescribing, PacifiCare supports the enumeration of health care providers by this method. Some states have objected to the use of physician DEA numbers to identify prescribers for electronic adjudication of prescription claims and use of the NPI would help to eliminate this issue. However, if the NPI is not available for e-prescribing use, we suggest that CMS utilize federal preemption authority over state laws to allow the continued us of other unique prescriber identifiers, such as the DEA number.

**Formulary and Medication History Standards**

The proposed rule also states that, "the standards should be vendor neutral and technology independent". PacifiCare is concerned about the recommendations by some of the stakeholders in the industry to use RxHUB, a proprietary software program, as a basis for a foundation standard. The adoption of the RxHUB protocol as a foundation standard could potentially stifle competition between existing vendors and discourage new vendors from entering the market. We strongly urge CMS to reconsider the formal endorsement of RxHUB or clarify the involvement of this entity in the standard setting process.

**II. Provisions of the Proposed Regulation**

**"PROVISIONS"**

**Eligibility**

The Centers for Medicare and Medicaid Services (CMS) has proposed making the ASC X12 278 Healthcare Services Review a standard for use in the MMR Part D when ANSI can incorporate functionality for real-time prior authorization messages for drugs. PacifiCare believes that the

X12 format does not conform to the MMA intent that disclosure of information should "be on an interactive, real time basis" and that CMS should consider using the NCPDP 5.1 telecommunications standard which provides for this real-time interaction.

The ASC X12 278 Healthcare Services Review format is intended for use in a batch process incorporating more than one claim or request. As such, it is not currently usable in the standard real-time (single request) format. The majority of pharmacy claim payers and Pharmacy Benefit Managers (PBMs) are operating in a real-time environment. A requirement to use the ASC X12 178, even if modified for real-time use, would present a significant challenge to the real-time industry. The NCPDP 5.1 telecommunications standard, version 5.1, currently provides the ability to include information and details to support a prior authorization request. The MMA standard should be modified to include the option of using the NCPDP Telecommunication standard, version 5.1, as an option for drug related prior authorization requests.

PacifiCare recommends that until the ASC X12 278 has incorporated real-time functionality, and has been adequately piloted and used in production in the provider and payer communities, it should not be a required standard. Alternately, CMS should allow providers and payers to use the NCPDP 5.1 Telecommunication Standard where applicable until such time as an acceptable industry standard can be defined.

**Submitter :** **Helen Yang** **Date: 04/05/2005**

**Organization :** **Wyeth Pharmaceuticals**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-46-Attach-1.DOC

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Lucinda E. Long
Vice President
Global Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

April 5, 2005

**BY ELECTRONIC SUBMISSION**

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P,
Box 8014
Baltimore, MD 21244-8014

**Re: CMS-0011-P (Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256)**

Dear Dr. McClellan:

Wyeth Pharmaceuticals welcomes the opportunity to comment on the proposed rule by the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* on February 4, 2005 ("proposed rule") on electronic prescribing standards under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research driven pharmaceutical and healthcare products companies with leading products in the areas of women's healthcare, cardiovascular disease, central nervous system, inflammation, hemophilia, oncology, and vaccines.

Section 1860D-4(e) of the MMA establishes a voluntary electronic prescribing (e-prescribing) program and requires the development of national e-prescribing standards. Beginning in 2009, the final e-prescribing standards will be mandatory for Medicare Part D providers who adopt e-prescribing in 2009. Based on recommendations from the National Committee on Vital and Health Statistics (NCVHS), CMS suggests the adoption of foundation standards as the basis for a more complete set of e-prescribing standards in the future.

Wyeth commends CMS for its efforts in the proposed e-prescribing rule to improve the quality of care for Medicare beneficiaries. Wyeth believes it is

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critical for an e-prescribing system to improve the quality of care and to strengthen the physician-patient relationship. In this spirit, we respectfully offer comments and recommendations to CMS in the following areas:

1) The impact of financial incentives for e-prescribing adoption on both prescribers and Medicare Part D sponsors,
2) The impact of e-prescribing adoption on health outcomes and quality of care,
3) The use of e-prescribing to facilitate enabling automatic prior authorization, and
4) Prescribing information and its presentation format through e-prescribing.

**Recommendations**

1) **CMS should not allow Part D sponsors that offer financial incentives to physicians for adopting e-prescribing to inappropriately influence physician prescribing behavior or restrict choice of medicines.**

The proposed rule allows Medicare Advantage plans to provide financial incentives to physicians for adopting e-prescribing under the Medicare Part D program in accordance with the established standards. These payments are intended to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. Accordingly, CMS will publish a proposed rule to create an exception under the Stark law for incentives related to e-prescribing. Also, the Office of Inspector General in the Department of Health and Human Services (HHS) will establish a safe harbor under the Anti-Kickback Statute.

As CMS indicated in the propose rule, "health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance.[1]" While we understand the goal of health plans to achieve positive returns on the costs associated with e-prescribing, Wyeth believes that health plans should not be allowed to use financial incentives to inappropriately influence physician's prescribing habits. The e-prescribing system should protect physician's

[1] Fed. Reg. Vol 70, No. 23, at 6269

prescribing autonomy and support physicians choosing treatment therapies primarily based on clinical judgment rather than cost concerns or financial incentives.

- In the final rule, CMS should ensure that the use of financial incentives do not inappropriately influence physician prescribing behavior or restrict provider choice and decision-making. For example, physicians should not be penalized or discouraged from prescribing clinically appropriate but off-formulary drugs if they deem these drugs to be the most appropriate treatment for their patients.

- CMS should also prohibit plans from incentivizing physicians solely on the basis of their performance in containing costs. For example, plans should not be allowed to set targets for generic prescribing or preferred tier prescribing and reward physicians on the basis of their performance in meeting those targets.

**2) CMS should examine the impact of e-prescribing adoption on health outcomes and overall patient quality of care.**

While e-prescribing is gaining acceptance by health care providers, CMS estimates that only 5 to 18 percent of physicians currently use e-prescribing.[2] The adoption rate is particularly low among solo practitioners, those in rural areas, and certain medical specialties.[3] Given many uncertainties about e-prescribing and possible unintended consequences, we recommend CMS give special considerations to the following areas in developing final e-prescribing standards and making implementation decisions.

- Wyeth believes that the primary drivers for e-prescribing adoption should be the improvement of patient safety and quality of care. However, plans have focused heavily on using e-prescribing to improve formulary compliance, increase generic utilization, and reduce pharmaceutical and administrative costs. We recommend that CMS conduct analyses of e-prescribing's impact on formulary compliance, generic utilization and their impact on patient care, health outcomes and overall quality of care.

[2] Fed. Reg. Vol. 70, No. 23, at 6260
[3] 69 Fed. Reg. at 46672

- In its analyses, CMS should recognize the potential unintended consequences of e-prescribing. For example, if plans are authorized to compensate prescribers who use e-prescribing on the basis of their performance on formulary compliance and/or whether meeting cost containment targets, patient access to medicines may be inappropriately limited by under-prescribing. Under-use of clinically appropriate treatments may not only have a negative impact on health outcomes but also increase the total healthcare costs. Studies have found that appropriate use of pharmaceuticals produces savings from reduced use of medical services as well as from improvements in patients' health, quality of life, longevity, and economic productivity.[4] A study conducted by Dr. Frank R. Lichtenberg concludes that each dollar increase in pharmaceutical spending yields a reduction in hospital expenses of $3.65.[5]

- CMS' analyses should also examine how the use of e-prescribing could maximize potential savings to the Medicare program through improvements in patient safety, quality of care, and health outcomes. These savings could be realized through:
  - reduction in medication errors and adverse events,
  - reduction in total healthcare costs due to appropriate drug utilization (e.g., from adherence to recognized clinical treatment guidelines),
  - improvements in patient medication compliance and persistency,
  - and more efficient communication and prescription transactions among prescribers, dispensers, and plan sponsors, through the use of tools such as automated prior authorization.

**3) E-prescribing system should be designed to allow for automated prior authorization at the point of care.**

Prior authorization (PA) is a requirement placed on certain drugs to encourage appropriate clinical usage and contain drug expenditures, especially for higher cost medicines (e.g., biologics) or therapeutic categories. NCVHS estimates that 2 percent of prescriptions are subject to PA requirements, and that there is

[4] Meyer, J. *Assessing the Impact of Pharmaceutical Innovation*, 2002
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a higher rate in the Medicaid program.[6] Prior authorization is now commonly used in prescription drug benefit programs administered by private health plans and Medicaid. According to the Medicare Payment Advisory Commission (MedPAC), it may be used even more frequently in the Medicare Part D program.[7]

The request for a prior authorization for a drug from the prescriber to the payer/Pharmacy Benefits Manager (PBM) is now conducted manually.[8] The manual processes, which may involve coverage denials at the pharmacy counter, phone calls among prescribers, dispensers and plans, and waiting periods for patients—are an administrative burden for patients, pharmacies and prescribers. As a result, medical staff time may be diverted from patient care and education to handling the voluminous paperwork and increased telephone calls from patients.[9] In addition, a manual PA process may require plans to hire extra personnel to handle prior authorization calls.

While PA may provide short-term savings to plans, it may have a negative impact on patient care. Because manual prior authorizations take time to be processed, they can result in unnecessary delays in patient treatment and higher administrative costs. A recent MaineCare study on prior authorization reports that some patients experience dangerous side effects or even a worsening of their medical conditions as they go through the PA process before they are allowed to take an effective medication that is subject to PA.[10] According to the report, consumers find the manual process confusing and frustrating. As a result, instead of trying to navigate the PA process, some patients will simply not get the prescribed medication while others will have to pay the full cost of a drug when told their plans will not cover it at the pharmacy counter.

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[6] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm
[7] MedPAC public meeting, March 10, 2005
[8] NCVHS Letter to HHS Secretary, *First set of recommendations on e-prescribing standards*, September 2, 2004. http://www.ncvhs.hhs.gov/040902lt2.htm
[9] *The MaineCare Advisory Committee's Prior Authorization Subcommittee Report and Recommendations on Prior Authorization for Prescription Drugs in the MaineCare and Drugs for the Elderly Programs*, January 19, 2005.
[10] Ibid.

Wyeth

The MaineCare report concludes that aspects of the current PA implementation have adverse consequences directly affecting patient care and medical practices of providers. These consequences may, in turn, result in hidden and unintended costs to the healthcare system.[11] To improve patient care by avoiding unnecessary delays and improving efficiency, Wyeth believes that the e-prescribing system should be designed to help facilitate and fully automate the PA process. In an automated PA system, physicians would be notified at the point of prescribing that a medicine is subject to PA and empowered to enter relevant information that would, if appropriate, provide immediate patient access to the drug.

For example, etanercept is a tumor necrosis factor (TNF) inhibitor indicated for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in patients with moderately to severely active rheumatoid arthritis (RA). Many plans impose prior authorization requirements on etanercept before RA patients are provided access to the treatment. Typically, plans request two types of data to process a prior authorization for etanercept: patient diagnosis and previous failed drug therapy(ies). Since the e-prescribing system provides real-time information regarding a patient's eligibility and benefits, including a requirement for PA as well as patient's medication history, physicians should be able to submit a PA request for etanercept through e-prescribing and be informed whether the application is approved at the point of care.

A fully automated PA process will improve patient quality of care, ensure prescribing efficiency and reduce prescribing costs. We believe that the value of an e-prescribing system would be significantly diminished if prescribers must manually submit PA requests. We urge CMS to consider NCVHS' recommendation that HHS should evaluate the economic and quality of care impacts of automating prior authorization communications between dispensers and prescribers and between payers and prescribers in its 2006 pilot tests. [12]

---

[11] *The MaineCare Advisory Committee's Prior Authorization Subcommittee Report and Recommendations on Prior Authorization for Prescription Drugs in the MaineCare and Drugs for the Elderly Programs*, January 19, 2005.

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**4) Standards for the e-prescribing user interface and presentation of drug lists and formularies should ensure that appropriate, accurate and up-to-date information is presented in a comprehensive and neutral format.**

The use of e-prescribing should not inappropriately steer or influence a physician's clinical decision-making or prescribing practices. The content and completeness of the information provided by the system, along with the structure, format, and organization of the formulary and user interface within the e-prescribing technology will undoubtedly impact and influence a provider's prescribing behavior. For example, if the initial e-prescribing interface only provides a list of generic or preferred innovator medicines covered by the plan and requires physicians to scroll through additional pages to access and prescribe alternative therapies, a physician's prescribing choices may be negatively impacted. Patients' access to needed medicines may also be effectively limited. We believe that CMS should be cognizant of these issues and develop standards that will guarantee comprehensiveness and neutrality in the e-prescribing process.

CMS should ensure that future rulemaking on standards for the e-prescribing user interface and presentation of drug lists and formularies address the following issues:

- Physicians should have easy access to the comprehensive list of available drugs and the information should be presented in a single, neutral, and comprehensive format (e.g., alphabetically).

- The user interface should not create barriers to prescribe non-preferred or off-formulary drugs. It also should not limit the ability of physician to prescribe drugs for clinically appropriate off-label uses.

- E-prescribing should not interrupt a physician's workflow—e.g., wading through multiple pages to view drug choices, or pop-up windows with information about formulary or prior authorization.

- The system should provide up-to-date, accurate, and comprehensive information to assist physician communicating with the patient at the point of care, such as information about appropriate drug utilization.

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- The system should also provide information needed for timely access by beneficiaries to clinically appropriate treatment, such as accurate and easy-to-understand information about exceptions and appeals.

- The system should be updated on a timely and frequent basis so that real-time information will be presented to ensure patient access to new drugs and drugs with new indications.

**Conclusion**

Wyeth believes that e-prescribing holds the potential to be used as a tool to reduce prescribing errors, improve patient safety, health outcomes and quality of care, and improve prescribing efficiency. To achieve these goals, e-prescribing should not be used to limit physician prescribing choices, or patient access to clinically appropriate medications. E-prescribing also should not inappropriately influence physicians' decision-making, interfere with physicians' workflow or impede their ability to make appropriate clinical and pharmacological choices.

We appreciate this opportunity to provide CMS with comments and recommendations on e-prescribing standards and the e-prescribing program under the Medicare Part D program. We look forward to working with CMS in future e-prescribing rulemaking and the implementation of the e-prescribing program. If there are any questions about Wyeth comments, please do not hesitate to contact me.

Sincerely,

Lucinda E. Long

**Submitter :** **Helen Yang** **Date: 04/05/2005**

**Organization :** **Wyeth Pharmaceuticals**

**Category :** **Drug Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-47-Attach-1.DOC

Wyeth Pharmaceuticals
500 Arcola Road
Collegeville, PA 19426

Lucinda E. Long
Vice President
Global Public Policy
484 865 5132 tel
484 865 6420 fax

Wyeth

April 5, 2005

**BY ELECTRONIC SUBMISSION**

Mark McClellan, M.D., Ph.D.
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P,
Box 8014
Baltimore, MD 21244-8014

**Re: CMS-0011-P (Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256)**

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[3] 69 Fed. Reg. at 46672

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Wyeth

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Wyeth

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**Conclusion**

Wyeth believes that e-prescribing holds the potential to be used as a tool to reduce prescribing errors, improve patient safety, health outcomes and quality of care, and improve prescribing efficiency. To achieve these goals, e-prescribing should not be used to limit physician prescribing choices, or patient access to clinically appropriate medications. E-prescribing also should not inappropriately influence physicians' decision-making, interfere with physicians' workflow or impede their ability to make appropriate clinical and pharmacological choices.

We appreciate this opportunity to provide CMS with comments and recommendations on e-prescribing standards and the e-prescribing program under the Medicare Part D program. We look forward to working with CMS in future e-prescribing rulemaking and the implementation of the e-prescribing program. If there are any questions about Wyeth comments, please do not hesitate to contact me.

Sincerely,

Lucinda E. Long

**Submitter :** **Mr. Kim Caldwell** **Date: 04/05/2005**

**Organization :** **DCEP/MDBG/CBC/CMS**

**Category :** **Federal Government**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-0011-P-48-Attach-1.DOC

**Comments to Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program**

## PROVISIONS:

### *F. Compliance Date (pg 6267)*

CMS proposes a compliance date of January 1, 2006 for the proposed foundation standards. By requiring Part D Sponsors to "support and comply with electronic prescribing" by January 1, 2006, this would require that all of their contracted pharmacy providers also must support and comply with these standards in that timeline. This timeline is on top of the already passed date for future Part D Sponsors to submit pharmacy access networks. By having conflicting requirements, CMS places the Plan Sponsors in harms way by having attestations bearing the weight of oath on pharmacy networks when the electronic prescribing standards may possibly remove pharmacies from availability to serve status.

We are requesting two things in this area, (1) that CMS change the wording to state that pharmacies willing and able to receive electronic prescriptions by 01-01-2006 comply with the industry approved standards while other pharmacies would be required to comply by a later date (2007 or 2008) if they remain in Part D networks and (2) that CMS comment on what will happen to those pharmacy providers that knowingly cannot comply within these standards and/or do not have the ability to accept electronic prescriptions in this timeframe due to circumstances beyond their control (e.g., cost barriers, technological barriers, etc.). For example, will CMS require that these pharmacies be excluded from contracts with Part-D sponsors if they do not meet the foundation standards by 01/01/06? This would further disadvantage those pharmacies that do not already have e-prescribing capabilities. Alternatively, would CMS allow for a grace period or extended timeline for compliance for pharmacies in these situations?

## IMPACT ANALYSIS:

### *D. Impact on Pharmacies and Other Dispensers (pg 6271)*

CMS comments that they do not expect to see "a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing." We disagree. There are three key areas for significant impact on pharmacies and other dispensers. First, electronic prescribing creates an environment in which prescriptions for many different patient types will benefit including those on Medicaid. Medicaid laws as followed in the states require that prescriptions must have a prescriber's *handwritten*

statement across the face of the prescription if a branded prescription is required when a generic is available. Even the wording is dictated. Without this possibility, pharmacies and pharmacists are at significant financial risk when their state pharmacy rules require no substitution if the physician indicates such yet the Medicaid language and audit procedures punish the pharmacists for dispensing the required brand without the prerequisite wording – a catch-22. State pre-emption is only intended to apply to Part D without regard for Medicaid or other prescriptions. Second, the potential exists for an increase in the total volume of prescriptions filled by pharmacies, since a proportion of hand-written prescriptions never reach the pharmacy and thus are not dispensed. Also, e-prescribing inherently promotes an increased utilization due to the menu driven approach to prescribing at the point of care.

Third, we agree with the expected efficiencies discussed at the beginning of this section, it is possible that an increase in e-prescriptions may result in an increase in the number of prescriptions that are not picked up by patients and therefore create additional administrative workloads for pharmacy staff.

A potential volume increase coupled with a condensed timeline for adoption, could potentially pose burdensome to pharmacies and other dispensers.

***G. Impact on Small Businesses (pg 6271-2)***

In the section on Impact on Pharmacies, it was stated that 75% of the 57,208 pharmacies already have e-prescribing capabilities and the majority of pharmacies are currently highly networked. Based on this information, it was assumed that the marginal cost of e-prescribing is likely to be small. However, the pharmacies referred to above are likely to be large business and/or chain pharmacies and may not represent the state-of-the-art for small and/or independent pharmacies. The proposed foundation standards will likely have disproportionably higher implementation costs for small pharmacies compared to large pharmacies. Also, small businesses will be less likely to absorb the implementation cost compared to larger pharmacies, especially given the delayed or minimal return on investment. Thus, if pharmacies are required to implement these foundation standards, certain pharmacies may decide not to contract with PDP Sponsors, particularly including: small/independent pharmacies, pharmacies in rural areas, and Indian Health Services/Tribes and Tribal Organizations/Urban Indian Health Program (ITU) pharmacies. This would most likely result in pharmacy access issues for geographical areas in which few pharmacy providers may be present. Most ITU and territory pharmacies do not operate with technology today, yet CMS mandates the inclusion of these pharmacies to meet pharmacy access standards.

**Submitter :** **Ms. Anne Canfield** **Date: 04/05/2005**

**Organization :** **Rx Benefits Coalition**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-49-Attach-1.DOC

**Rx BENEFITS COALITION**

**Safety + Affordability + Innovation**

May 3, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Madams/Sirs:

The Rx Benefits Coalition (RxBC), a coalition representing a diverse group of employers and other payers and providers of prescription drug benefits committed to ensuring that consumers have access to safe and affordable prescription drug services, The RxBC appreciates the opportunity to submit its comments in response to the Notice of Proposed Rulemaking (NPRM) implementing section 1860D-4(3) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA), which the Center for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (HHS) issued on February 4, 2005. 70 *Fed. Reg*. 6256-6274.

This comment letter discusses both the rule that HHS will promulgate based on comments to the NPRM (referred to in this letter as the Interim Rule), and the rules adopting additional standards that, according to the NPRM, HHS intends to promulgate in the future based on pilot testing of additional standards and functions necessary to the full implementation of the Part D electronic prescribing program (referred to in this letter as the Final Rules). The RxBC is primarily concerned with two subjects mentioned in the background section of the NPRM – the extent to which the standards promulgated under the Interim and Final Rules will preempt state law, and the structure of the standards approval process created by the Interim Rule.

**SCOPE OF PREEMPTION**

BACKGROUND, A. Statutory Basis, 2. State Preemption

PROVISIONS, B. Proposed Definitions

801 Pennsylvania Avenue, NW · Suite 625 · Washington, DC 20004
Tel: (202) 661-2100 Fax: (202) 661-2101
www.rxbc.org

*Statutory Basis*

*NPRM, page 6257. "We believe the best reading of [Section 1860D-4(e)(1)]- as well of the intent of Congress, is that the e-prescribing standards apply only to information regarding Part D eligible individuals enrolled in Part D plans, . . . We believe that this interpretation realizes the intent of the Congress, which in the Conference Report for the MMA, stated that e-prescribing standards are standards that apply to information, transmitted 'under an electronic prescription drug program conducted by a PDP or MA plan.' . . . This statement contemplates that the e-prescribing standards would apply solely to information regarding Part D enrolled individuals, not simply to information regarding Part D eligible individuals who are not enrolled in a Part D plan."*

*State Preemption*

*NPRM, page 6258-59. "The MMA addresses preemption of State laws at section 1860D-4(e)(5) of the Act as follows:*

> *(5) Relation to State Laws. The standards promulgated under this subsection shall supercede any State law or regulation that –*
>
> *(A) Is contrary to the standards or restricts the ability to carry out this part; and*
>
> *(B) Pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.*

. . .

*"We view [section 1860D-4(e)(5)] as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards, or that restrict the ability to carry out (that is, stand as an obstacle to) the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. Consequently, for a State law or regulation to be preempted under this express preemption provision, the State law or regulation would have to meet the requirements of both paragraphs (A) and (B)"*

. . .

*"We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities."*

We wish to make the following key points with respect to preemption of state laws and regulations that conflict or interfere with e-prescribing and the MMA:

1. The narrow interpretation of the preemption language proposed in the NPRM conflicts with the express intent of Congress and would greatly impede e-prescribing when the Interim Rule is adopted. In its current form, the NPRM merely adds one more narrow set of rules for e-prescribing standards on top of the confusing web of state legal restrictions. If enacted as proposed, this interpretation will impede the timely development, implementation and adoption of an effective uniform, interoperable, nationwide e-prescribing system.

2. Rather than issuing a narrow interpretation, HHS should clearly state that the standards adopted in the Interim and Final Rules issued by HHS preempt state laws or regulations to the extent that they affect e-prescribing . Only then can the HHS regulations facilitate an interoperable e-prescribing system within the timeframe envisioned in the MMA.

3. If HHS is not ready to issue regulations that clearly and effectively preempt the conflicting state laws and regulations, then it should postpone addressing preemption until it issues standards in all areas of the electronic prescription drug program and obtains information from the conclusion of the pilot testing that the MMA requires.

4. HHS should reserve for itself in the Interim Rule the authority to establish a flexible guidance process so that the Department can issue handbooks or other written guidance without needing to reopen the formal regulatory process.

5. For e-prescribing to become a reality, HHS should incorporate in the Final Rule all of the functions that are necessary to create a uniform, interoperable, nationwide set of standards.

In addition to presenting the policy arguments in support of these positions, this comment letter includes Attachment A, a legal analysis of the application of existing case law to the preemption language of Section 1860D-4(e).

## I. The Scope of Preemption Proposed in the NPRM Should be Broadened so that the Standards Issued Under the Interim and Final Rules Facilitate Rather than Impede Nationwide e-Prescribing and Thereby Help to Lower Healthcare Costs and Improve Patient Health

For e-prescribing to succeed, comprehensive uniform, interoperable, nationwide standards are essential. Without federal preemption that is not possible.

The NPRM itself recognizes that e-prescribing will bring many benefits to the American healthcare system. The U.S. healthcare delivery system currently is complex, inefficient, and highly fragmented. The Institute of Medicine has concluded that the

application of health information technology can improve both the efficiency and the quality of healthcare.[1]

The application of such technology to prescriptions is an especially important source of potential improvements. Patient health will benefit from a reduction in medication errors and adverse drug events which, according to the Institute of Medicine, account for over 770,000 injuries or deaths each year in hospitals. E-prescribing can reduce the incidence of medication errors by, among other things, helping to prevent illegible scripts and by providing prescriber access at the point of prescription to information about potentially dangerous drug interactions. One study cited by the Institute for Safe Medication Practices (ISMP) found a 55 percent reduction in medication errors after e-prescribing was instituted.[2]

E-prescribing also can reduce the burdens and costs on physicians and pharmacists The NPRM cites estimates that almost 30 percent of prescriptions require pharmacy callbacks that result in 900 million prescription-related telephone calls placed annually. (NRPM, p. 6260). Electronic interactions through e-prescribing can greatly reduce the number and extent of such interruptions for prescribers, dispensers and patients. As the NRPM concludes (p. 6260), "…even small improvements in quality that are attributed to e-prescribing may translate into significant health benefits."

### A. E-Prescribing Requires Nationwide Standards That Allow for Development and Implementation of Interoperable Electronic Systems

*The MMA's Comprehensive Approach to E-Prescribing*

Due to these acknowledged benefits, the MMA created a comprehensive electronic prescription program for payors, providers and pharmacies that manage benefits and prescribe and dispense covered Part D drugs. Congress did not expressly mandate the adoption of e-prescribing by Prescription Drug Plans (PDPs), Medicare Advantage Organizations offering Medicare Advantage-Prescription (MA-PDs) plans or providers, but provided that HHS would promulgate uniform standards for those that do adopt e-prescribing. In the NRPM, however, HHS would mandate that PDPs and MA-PDs implement electronic prescribing and that the programs utilizing the foundation standards would be available on January 1, 2006. While participation by providers and pharmacies is voluntary, some will utilize e-prescribing because of contractual requirements of a health benefit plan in which they participate.

The MMA requires that e-prescribing include real-time electronic delivery of certain specific information on eligibility, benefits, drug interactions, warnings, dosage

[1] Institute of Medicine, To Err Is Human: Building a Safer Health System (Washington, DC: November 1999) and Crossing the Quality Chasm: A New Health System for the 21st Century (Washington, D.C.: March 2001).

[2] Institute for Safe Medication Practices (ISMP), white paper, "A Call to Action: Eliminate Handwritten Prescriptions Within 3 Years!" 2000.

adjustments, medication history, and the availability of generic substitutes to providers and pharmacists. This information must be provided in a secure format that complies with health privacy requirements. The system also must permit the electronic exchange of FDA drug labeling and listing information. E-prescribing systems are intended to provide a near-term foundation for the continuing implementation of systems for electronic medical records.

The MMA contains a statutory requirement for HHS to issue regulations that provide standards for e-prescribing that pertain to electronic prescribing programs. It sets an aggressive schedule for issuance of the e-prescribing standards and their implementation.

*The Need for E-Prescribing Incentives*

Three factors are critical to the development of a nationwide e-prescribing capability. First, the parties who benefit from e-prescribing must have flexibility to compensate one another and create incentives for prescribers and pharmacies to adopt new e-prescribing systems. This is needed because participation in e-prescribing – especially by physicians – is voluntary. Physician reluctance to adopt new e-prescribing technologies has been well documented.[3]

Moreover, the adoption of e-prescribing systems involves externalities; the benefits also accrue to other parties besides the physician or pharmacy that adopts the system. The MMA recognizes this and authorizes the Secretary of HHS to provide incentive payments to physicians to help defray their costs. The MMA also provides for a safe harbor from federal anti-kickback laws and an exemption from federal limitations on physician referrals (the "Stark law") so that stakeholders in the e-prescribing network can compensate one another for joining.

*The Need for Scale*

The second critical factor in e-prescribing is scale. In other words, similar to the expansion of the telephone or Internet, the e-prescribing system will offer increasing benefits that multiply according to the number of participants in the system. To achieve scale requires that as many appropriate parties as possible – physicians, pharmacies, hospitals, pharmacy plans, pharmacy benefit managers, etc. – be included in the expanding network. Scale also requires a nationwide system that is accessible by parties who are located in all parts of the country. Again, the MMA recognizes this and requires HHS to issue regulations to create national uniform standards that preempt any state law or regulation that conflicts or interferes with the e-prescribing program. This preemption

[3] "In health care, the average investment in information technology computer hardware, software, and services is only about $ 3,000 annually for each worker, compared with $ 7,000 a worker on average for private industry and nearly $ 15,000 a worker in banking….But health care remains a fragmented industry, with much of the care still provided by physicians in small practices." Steve Lohr, "Health Industry Under Pressure to Computerize," *New York Times*, February 19, 2005.

would include standards that pertain to the electronic transmission of a medication history as well as information on eligibility, benefits, and prescriptions for covered Part D drugs.

*The Need for Interoperability*

The third necessary element in e-prescribing is interoperability. As used in this comment letter, the term includes interoperability not only in the more narrow technical sense, but also operationally. The history of electronic technology development is littered with multiple systems that could not talk to one another. Today, even companies that produce potentially proprietary information technology systems recognize the benefits of interoperability.[4] This relates to scale. With interoperability, the participants in an information network reap substantially greater benefits than if that network is divided into smaller fiefdoms.

Again, the MMA addresses this issue in multiple ways.[5] In order to institute a nationwide e-prescribing system, MMA requires the Secretary of HHS, with recommendations by the National Committee on Vital Health Statistics (NCVHS), based on consultations with a range of industry and government stakeholders, to adopt, recognize, or modify uniform standards for the e-prescribing program. The Secretary must develop initial standards by September 1, 2005 and must pilot test them beginning in 2006 unless the Secretary determines that the initial standards reflect "adequate industry experience." Final standards must be in place by April 1, 2009.

To assure interoperability, and preclude the division of the country into separate areas that might lack access to the common e-prescribing network, the MMA provides that the standards will preempt state laws and regulations that conflict or interfere with e-prescribing programs. That preemption is needed to assure both the scale and interoperability that are required for a successful nationwide system.

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[4] See, e.g., Steve Lohr, "High-Tech Alliance on Base for a Digital Health Network," *New York Times*, January 26, 2005. ("Eight of the nation's largest technology companies, including IBM, Microsoft and Oracle, have agreed to embrace open, nonproprietary technology standards as the software building blocks for a national health information network.")

[5] In addition to creating the Electronic Prescription Drug Program, the MMA provides for a number of initiatives that relate to electronic or technology-enabled programs to reduce costs and improve quality of care. These initiatives include: a) grants to physicians to implement electronic prescription drug programs (Section 101); b) an IOM Study on Safety and Quality to provide a blueprint for system-wide change (Section 107); c) an IOM Study on Performance Measures to identify information technology requirements in aligning performance to payment for service (Section 238); d) an extension of telemedicine demonstrations and doubling the available authorized funding for patient safety improvements using information technology (Section 417), e); a 3 year CMS pay-for-performance demonstration program using health care information technology at 4 separate sites (Section 649); f) establishment of a new Council for Technology and Innovation within CMS for oversight of technology enhancements (Section 942), g) establishment of a new Commission on Systemic Interoperability to focus on standards development acceleration and adoption (Section 1012); and h) creation of a health care infrastructure loan program including $200 million in grant funding over 54 months for loans to providers to implement technology (Section 1016).

### B. E-Prescribing Can Become a Practical Reality Within the Timeframe Mandated by the MMA Only if HHS Adopts A Broad Scope of Preemption That Effectively Preempts Those State Laws and Regulations That Conflict With the Standards

The e-prescribing regulations that HHS will issue to implement the MMA have the potential to help overcome the significant barriers to e-prescribing. The NPRM, however, takes a cautious approach that should be modified in the Interim Rule if it is to help, rather than hinder the expansion of an e-prescribing network.

The primary impediment to achieving the scale and interoperability needed for e-prescribing is the patchwork of laws and regulations in the 50 states, the District of Columbia, Puerto Rico, etc. Section 1860D-4(e)(5) of the MMA addresses this impediment in clear language. In our view, the MMA directs HHS to issue standards that preempt any state law or regulation that conflicts or interferes with the standards pertaining to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs and that is contrary to the standards or restricts the ability to carry out the MMA.

Unfortunately, the NPRM proposes to limit (p. 6257) any preemption to prescriptions with respect to covered Part D drugs *prescribed for Part D eligible individuals*. As is discussed further in Appendices A and B to this comment letter, this approach unreasonably narrows the scope of the MMA with respect to e-prescribing. E-prescribing depends on the ability of prescribers and other members of e-prescribing networks to conform their e-prescribing systems to a single set of standards that apply across the nation. The public is not well served by policies that permit conflicting state laws and regulations to preclude a nationwide e-prescribing system.

Virtually all payors' and providers' patient population bases are served by many different benefit programs. Applying the standards only to Part D beneficiaries for covered Part D drugs creates multiple problems. In states that prohibit e-prescribing, for example, a prescriber would create an e-prescribing system exclusively for prescriptions for Part D individuals, while continuing to prescribe by hand for all other prescriptions for those states.[6]

In states that permit e-prescribing but have laws or regulations that conflict with the standards that will be issued by HHS, a prescriber who wants to electronically prescribe for all patients will be required to maintain two e-prescribing systems, one for patients enrolled in Medicare Part D and one for all other patients. In multi-state areas, such as the Washington, D.C. metropolitan area, where physicians practice across state lines, this problem is multiplied. In reality, most prescribers cannot determine who the payors will be. They will not go through the expense of maintaining two or more

[6] The testimony of the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004, identifies South Carolina and South Dakota as states that do not allow electronic transmission of prescriptions. See p. 10.

systems and will elect not to e-prescribe at all; physicians will simply continue to use paper prescriptions.

Also, in cases where Part D coverage might be denied for a patient at a time after the physician has written a prescription for an eligible Part D drug,[7] the physician then would face the prospect of being found in violation of a state law or regulation that otherwise would have been preempted. The pharmacy that dispensed the prescription would also find itself at legal risk. Limiting preemption to Part D enrollees rather than covered Part D drugs is simply not practical.

Besides the fact that certain states prohibit e-prescribing outright, the most important problem that exists involves the myriad of often small differences between state laws or regulations. Cumulatively, these differences can prevent e-prescribing from achieving needed scale and degree of coverage to be attractive to many prescribers. For example, specific electronic authentication requirements differ among the states, as do requirements about whether the physician may transmit the prescription to the pharmacy through an intermediary, such as a router. Another potential impediment for prescribers is the variation in state laws with respect to the format of prescriptions. A national standard for the format of prescriptions is needed to achieve a uniform, interoperable nationwide system for electronic prescribing. Only with such a standard format can the needs of elderly patients who may travel from their homes and their prescribing physicians to warmer climates in the winter and for those physicians practicing in multi-state jurisdictional areas be accommodated.

While any one standard may be beneficial, a multiplicity of requirements makes uniform, interoperable, nationwide system for e-prescribing difficult, if not unworkable. Consider the following state requirements presented in testimony of the National Association of Boards of Pharmacy (NABP) to the NCVHS Subcommittee on Standards and Security[8]:

- The states of Nevada and Ohio require that the state Board of Pharmacy approve the e-prescribing system (NABP, pp. 10 and 13).
- The state of Washington requires such Board approval every three years (NABP, p. 17).

[7] This could occur, for example, in some cases where a patient may have dual coverage and receives a Part D drug that is not eligible to be paid for under Part D. *See* the Notice of Proposed Rulemaking dated August 3, 2004, 69 *Fed. Reg.* 46632-46863 implementing the Medicare Part D benefit at page 46647 where HHS discussed the complexity of determining whether a drug prescribed for a Medicare beneficiary was a covered under Part D or under Part A or B. By way of example, the NPRM pointed out that "Part D would cover immunosuppressive drugs furnished to Medicare beneficiaries who did not have their transplant paid for by Medicare (*e.g.*, a beneficiary who had his or her transplant paid for by a private insurer when he or she was employed, and the beneficiary has now enrolled in Part B). Part D could pay for these immunosuppressive drugs for these beneficiaries since Part B is prohibited by statute from paying for them."

[8] *Ibid*. at the pages indicated.

- In Maryland, any "commercial intermediary must guarantee the confidentiality and security of transmission process in a manner approved by the Board" (NABP, p. 6).
- The states have varying requirements for prescription forms. For example, the state of Alabama allows electronic transmission but requires that the prescriber must write "Brand Medically Necessary" whenever a specific brand must be dispensed (NAPB, p. 1).
- The states have a variety of requirements concerning whether a prescriber may provide the electronic prescription to a pharmacy through an intermediary and the nature of permitted intermediaries.
- The states have a variety of electronic signature requirements.

A copy of the NABP table of state requirements is appended to this comment letter as Attachment B.

Such requirements are serious obstacles to the expansion of e-prescribing. For example, the requirement for board approval of the system creates the risk that the board of pharmacy of a single state might preclude operation of an e-prescribing system in which the e-prescriber has made a significant investment and which is acceptable under the rules of other states. It also risks freezing the level of technology in cases where a board publishes an approved list of e-prescribing systems that is only infrequently updated.

Depending on the state, some of the conflicting requirements are set by law while others appear in board of pharmacy rules and interpretations. Indeed, such rules and interpretations can be more troublesome than state statutes because (1) they can often be proposed and adopted with little public notice (as compared to state statutes) and (2) they can be difficult for a party to obtain, compared to statutes that the states codify.

Prescribers face significant sanctions if their e-prescribing fails to comply with each of the variable and changing state requirements. This creates enough uncertainty that prescribers are unlikely to actively implement an e-prescribing system even if they were able to achieve technical compliance with each state's requirement at a particular time. At a minimum, technology vendors are likely to avoid service to states where the requirements are onerous, unclear, or at variance with requirements of a number of other states. The Government Accountability Office observes:

> "[H]ealth care providers are uncertain about what would constitute violations of those laws or create a risk of litigation. To the extent that there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT."[9]

[9] *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, p. 44.

In summary, preemption of conflicting state laws is needed to make sure that the MMA, as implemented by HHS in its regulations, in fact leads to creation of nationwide, uniform, interoperable standards. Otherwise, e-prescribing cannot succeed except at the margins.

### C. If HHS is Not Ready to Take the Needed Broad View of Preemption, Then it Should Defer its Analysis of Preemption Until HHS (A) Issues the Complete Set of Standards Needed for E-Prescribing Under the MMA, and (B) Evaluates the E-Prescribing Pilot Tests

The MMA does not require HHS to issue regulations defining the scope of that preemption. Rather, the preemption language at Section 1860D-4(e)(5) is self-executing: the standards themselves automatically preempt conflicting or burdensome state laws and regulations. The purpose of any HHS action to define the scope of preemption in regulations should be to make the process of implementing the standards as smooth as possible to facilitate and encourage their adoption so that HHS can meet the tight deadlines for e-prescribing that the MMA sets.[10]

If HHS is not ready to take the view of preemption that is needed to assure that e-prescribing is implemented within the timeframes set by the MMA in the context of the Interim Rule, then we respectfully urge that HHS should remain silent in the current rulemaking. Instead, HHS should defer presenting any analysis of preemption until it issues all of the standards for e-prescribing that are envisioned under the MMA. Additionally, HHS should wait until information is available from the pilot testing that the Department is undertaking. We urge that HHS utilize its pilot tests to explore the need for preemption and the necessary scope. Then the pilots can reveal clearly to HHS the burdens on e-prescribing that conflicting state laws and regulations impose.

It is premature to narrow the scope of preemption in the present rulemaking, before the entire group of standards has been issued and information from the pilot tests is available. Otherwise, e-prescribing will remain a dream rather than a practical reality for many years to come.

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[10] The HHS responsibility to preempt state laws and regulations that are contrary to or restrict federal e-prescribing standards derives from the language of the MMA itself. President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335 provides additional reason for HHS to give the preemption provisions of the MMA a practical rather than restrictive interpretation. That executive order calls upon HHS, among other requirements, to, "[a]dvance the development, adoption, and implementation of health care information technology standards nationally through collaboration among public and private interests, and consistent with current efforts to set health information technology standards for use by the Federal Government"

The NPRM mentions President Clinton's Executive Order 13132 on federalism, as the basis for its cautious approach so that the proposed new regulations would narrow the degree of preemption permitted under the MMA. However, the NPRM omits to acknowledge this more recent executive order that provides a basis for assuring that preemption is appropriate for the department's mandate to meet the MMA's aggressive timetable for adoption of e-prescribing standards.

## II. Legal Analysis Demonstrates that Congress Intended the MMA's Preemption Provisions to have Broad Application

The NPRM (p. 6259) invites comments on its proposed position that Section 1860D-4(e)(5) of the MMA that preempts state laws should be interpreted in a manner that provides for "conflict" preemption as opposed to "field" preemption. The NPRM also requests comments on whether: (1) there are state laws that should be preempted (presumably in order to achieve the goals of the MMA) that would not be preempted under HHS' more narrow interpretation, and (2) the preemption provisions apply only to transactions and entities that are a part of an Electronic Prescription Drug Program under Part D or to a broader set of transactions and entities.[11]

These comments will first demonstrate that Congress expressly provided for broad, i.e., "field" preemption at least with regard to all aspects of an e-prescribing program. In support of this position, we will point out state laws that could interfere with e-prescribing programs that may not be interpreted as being in direct conflict with standards promulgated by HHS and the potential threats to adoption of e-prescribing programs raised by HHS asserting a narrow interpretation of the preemption provisions at this time. Since Congress intended to preempt the "field" of at least e-prescribing programs, the preemption provisions apply to any state laws or regulations that are not only contrary to but that restrict the ability to carry out such programs.

### Congress Expressly Preempted the Field of E- Prescribing

#### A. The MMA Covers the Field of E-Prescribing Programs

[11] We are responding to the manner in which HHS has posited this issue. We note, however, as set forth in Attachment A, that Congress has expressly and broadly preempted state law based upon the plain reading of the language of section 1860D-4(e)(5)and other principles of statutory construction. The issue of field versus conflict preemption arises in cases in which preemption is not express but implied, which is not the case here. We would point out here that "Established principles of implied preemption" support a broad view of the scope of preemption Congress adopted in the MMA. Even without an express preemption provision, the Supreme Court has found that "state law must yield to a congressional Act in at least two circumstances." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). First, "when Congress intends federal law to 'occupy the field,' state law in that area is preempted." *Id*. (When Congress chooses to occupy the field, state law can be preempted even if Congress chooses not to regulate a specific aspect of the "occupied" field. *See Chamber of Commerce of the U.S. v. Lockyer*, 364 F.3d 1154, 1169 (9th Cir. 2004).) Second, even if Congress has not occupied the field, state law is preempted to the extent of any conflict with a federal statute. *Crosby*, 530 U.S. at 372; *see English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Such a conflict exists either where (1) compliance with both the state and federal law is "a physical impossibility," or (2) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Moreover, Congress' inclusion of an express preemption clause "'does *not* bar the ordinary working of conflict preemption principles.'" *Sprietsma v. Mercury Marine*, 537 U.S. at 65 (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in *Geier*)). *Boggs v. Boggs*, 520 U.S. 833, 844 (1997) (quoting *Gade v. Nat'l Solid Wastes Management Assn.*, 505 U.S. 88, 98 (1992)).

A legal analysis of the federal common law on preemption and statutory construction as applied to the preemption provisions is attached as Appendix A. Without repeating the points of Appendix A, this analysis will focus specifically on the NPRM's position and request for comment.

The main support in the NPRM's proposed interpretation for its "plain language" interpretation of the preemption provisions is Congress' use of the term "and" between parts (A) and (B). The NPRM's attempt to narrow the scope of the preemption intended by Congress fails under the NPRM's own analysis.

In order to properly assess the intent of Congress, the language of the statute needs to be considered along with the full scope of the MMA and the Part D benefit. Congress recognized that e-prescribing was an important step in establishing an electronic infrastructure for the U.S. health care system. Thus, Congress mandated these broader initiatives because it recognized that multiple barriers exist and those barriers will prevent the development of an e-health infrastructure . See footnote 5 *supra*.

In addition, the meaning of the term "standards' is important. Congress intended that a comprehensive drug benefit and attendant health care components would be greatly enhanced by an electronic prescribing program. As such, the statutory scope of the term "standards" is very broad.[12] These standards address not only the transmission of information but also, as the MMA specifies, the actions necessary to insure that the objectives of patient safety, quality of care and efficiencies and cost savings are met. §1860D-4(e)(3)(B). Because the MMA includes requirements for patient compliance and care management program as an integral part of the Part D benefit, it is clear that the term "standards" as used in the express language that "[t]he *standards* promulgated under this section shall supersede any state law or regulation …" was intended to refer to all of the components of an electronic prescribing program as it supports the Part D benefit. § 1860D-4(e)(5) (emphasis added).

This plain reading of this language is further bolstered by the additional language Congress included in part (A) that the state laws that are superseded include not only

[12] Congress defined the Part D benefit to include far more than the cost of the drugs. As a component of the Part D benefit, beneficiaries are entitled to the following: (1) access to drug specific information on covered Part D drugs, including through pharmacy networks, how a PDP or MA-PD formulary functions and how a beneficiary can obtain access to information about access to covered Part D drugs and pharmacy networks, formularies and beneficiary cost-sharing requirements, (2) mechanisms for responding to beneficiary questions and providing information via the Internet about changes to formularies and explanations of benefits, (3) access to pharmacies, (4) meeting requirements for development of formularies that must include products in every therapeutic category and periodic evaluations of treatment protocols and procedures, and (5) cost and utilization management, quality assurance and medication therapy management programs. The medication therapy management programs are targeted to beneficiaries with multiple conditions, taking multiple drugs and likely to exceed drug spending targets set by HHS. The elements of the program include patient compliance regimens, (refill reminders, special packaging and other programs and means), and coordination with chronic care improvement programs. By definition, the full scope of the Part D benefit goes far beyond the act of paying for covered Part D drugs and includes a broad set of entities and transactions.

laws that are "contrary to" the standards but also (through the term "or") any state law or regulation that "*restricts the ability to carry out this part*." § 1860D-4(e)(5) (emphasis added). The term "part" is clearly defined in the statute to include all of the Part D benefits including access, utilization, quality assurance and care management programs. Part (A) clearly includes the disjunctive term "or" between "contrary to the standards" and "restricts the ability to carry out." The NPRM's interpretation hinges only on the "contrary to the standards" language and improperly reads the "restricts the ability to carry out this part" language of part (A) totally out of the statute.

Moreover, the use of the term "and" between (A) and (B), even if read as "conjunctive," does not eliminate the application of "restricts the ability to carry out this part" language in (A). Even under the NPRM's proposed reading, the statute expressly requires any standard promulgated by HHS to preempt any state law or regulation pertaining to the transmission of medication history and of information on eligibility, benefits and prescriptions with respect to covered Part D drugs under this part that "**restricts the ability to carry out this *part***…."

That it is essential to give meaning to this phrase in part (A) is made clear by an examination of the language in part (B). The term "pertains" is very broad and applies to the "transmission of electronic information" in all of the elements of the electronic prescription drug program as defined in Part D: 1) medication history, 2) information on eligibility, 3) benefits (which include access to information, formulary, pharmacy networks, beneficiary cost-sharing, explanation of benefits, quality assurance and medication therapy management programs), and 4) prescriptions. Given the full scope of benefits provided under Part D, the phrase "with respect to covered part D drugs under this part," must of necessity include all aspects of an electronic prescribing program, compelling the conclusion that 1860D-4(e) applies to medication history and the other components with respect to covered Part D drugs prescribed for any individual, not just for Part D eligible individuals.

### B. Common Sense Further Supports Express Preemption of the "Field" of E-Prescribing Programs

Existing state laws and regulations apply to all participants in an electronic prescribing program, including the NPRM-identified stakeholders (p. 6260) of prescribers, pharmacists and associated staff, vendors, hospitals and health systems, patients, health plans, and pharmacy benefit managers, among others. The only parties that potentially would not be participants in Part D benefits are those providers that treat only children, i.e., pediatricians and children's hospitals or physicians or other providers who do not accept assignment of Medicare (even these may have patients who pay them out of their pocket, but who would receive Part D benefits). State laws and regulations, however, do not tend to make any distinction among the type of patient treated, e.g., child as opposed to adult. In the same vein (apart from Medicaid and similar programs), state laws and regulations do not tend to make any distinctions based upon the party that is paying for the benefit, whether it is paid for by Medicare, commercial insurance or out of a patient's pocket. Accordingly, the distinction that HHS seeks to impose between

covered Part D drugs received by Part D enrollees and the same drugs received by others merely adds another complication to the pattern of state laws and regulations that already conflicts with e-prescribing.

As set forth previously, there are many examples of state laws and regulations that are not clearly preempted by the NPRM's "contrary to" approach. For example, consider the difficult scenario where the states impose additional prescriber or pharmacy identifiers or requirements different from the federal identifier that the NRPM proposes be promulgated. This may not constitute a "conflict" for purposes of the preemption language of the proposed rule. Given the patchwork of laws on this and related topics under electronic prescribing, this would certainly create havoc in the industry, including for PDPs and MA-PDs that have multiple state jurisdictions to serve.

Common sense and the clear evidence of Congress' awareness of problems that exist compels conclusion that Congress intended expressly to preempt the field of electronic prescribing programs for covered Part D drugs prescribed for any individual.

## III. The Final Rule Should Include In The E-prescribing Standards All Of The Functions Necessary To Facilitate E-Prescriptions

As noted at the beginning of this comment letter, a uniform standard that includes all of the components necessary to e-prescribing is critical if an effective nationwide interoperable e-prescribing system is to become a reality. The NPRM at page 6262 identifies a number of functions that NCVHS in its September 2, 2004 letter to the Secretary that should be included in "standards needed for the interoperable electronic exchange for most of the categories of information enumerated in Section 1860D-4(e)(2)" of the MMA. In addition to the functions identified in the NPRM, NCVHS in its March 4, 2005 letter to the Secretary beginning at page 10 identifies "a number of message format, terminology, and identifier standards and important related issues associated with e-prescribing" that should be considered in the context of developing Part D e-prescribing standards. We believe it is essential to incorporate most, if not all, of those functions in the standards promulgated under the Final Rule and, as indicated earlier in this comment letter, that the standards preempt all state laws and regulations that impede or conflict with the implementation of a nationwide interoperable e-prescribing system.

In addition to the functions identified in the September 2, 2004 NCVHS letter and expanded upon in the March 4, 2005 letter, the Final Rule should also include any other remaining functions that were not identified in those letters but are important to the creation of a nationwide interoperable e-prescribing system. Examples of those functions include, but are not limited to a standard drug prescription format that can be used in all jurisdictions; a standard rule that implements the Stark (anti-referral) exception and the anti-kickback safe harbor promulgated by the Secretary pursuant to Section 1860D-4(e)(6) of the MMA that would be the sole rule applied in all jurisdictions; a standard that addresses authentication of electronic prescriptions across jurisdictions; and others.

*Proposed Definitions*

*NPRM, page 6265. "We propose to amend Section 423.159 of the Medicare Prescription Drug Benefit final rule to add definitions pertinent to the e-prescribing process and to amend the title of the section to be consistent wit the term "Electronic Prescription Drug Program" which we are proposing to define below. The proposed definitions are as follows:*

. . .

- *Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.*

. . .

- *Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."*

Based on our view that Congress intended to have the e-prescribing standards adopted by the Secretary under Section 1860D-4(e) apply to covered Part D drugs prescribed for any individual – rather than be limited to covered Part D drugs prescribed for Part D eligible individuals – the definitions of "Electronic Prescription Drug Program" and "Prescription-related information" in Section 423.159(a) of the proposed regulation (NPRM, p. 6273) should be revised to read as follows:

> "Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs ~~prescribed for Part D eligible individuals who are enrolled in Part D plans~~."
>
> "Prescription-related information means information regarding eligibility for drug benefits, mediation history, or related health or drug information for ~~Part D eligible~~ individuals ~~enrolled in a~~ *for whom covered* Part D ~~plan~~ *drugs are electronically prescribed*."

**STANDARD SETTING PROCESS**

BACKGROUND, A. Statutory Basis

BACKGROUND, F. Evolution and Implementation of an Electronic Prescription Drug Program

Also relates to BACKGROUND, H. Summary of Status of Standards for an Electronic Prescription Drug Program

*Statutory Basis*

*NPRM, p. 6257. "In order to provide for efficient implementation of the requirements, section 1860D-4(e)(4)(C) of the Act requires the Secretary to conduct a pilot project to test initial standards developed under section 1860D-4(e)(4)(A) of the Act, prior to issuing the final standards that are promulgated in accordance with section 1860D-4(e)(4)(D) of the Act. Section 1860D-4(e)(4)(C)(ii) of the Act also permits an exception to this pilot testing requirement to the pilot testing requirement for standards for which there already is adequate industry experience, as determined by the Secretary after consultation with affected standard setting organizations and industry users. Under this exception, standards can be proposed and adopted through rulemaking as final standards without pilot testing, and would then become final standards under MMA."*

*Evolution and Implementation of an Electronic Prescription Drug Program*

*NPRM, p. 6261. "In this regulation, we propose to adopt foundation standards (that is, standards that do not need to be pilot tested because adequate industry experience with those standards already exists). While the statute includes an exception to the pilot testing requirement for standards with adequate industry experience, it does not define the term…We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions and we solicit comments on these criteria:*

- *The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

- *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

- *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected."*

*Summary of Status of Standards for an Electronic Prescription Drug Program*

*NPRM, p. 6264. "…At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience…We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication and could serve as foundation standards."*

*Evolution and Implementation of an Electronic Prescription Drug Program*

*NPRM, p. 6261. "We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS."*

**Standards Approval Should Not be Dependent upon ANSI Accreditation**

For the development and implementation of standards under the e-prescribing system, the NPRM offers for comment three criteria to give meaning to the statutory requirement that a candidate foundation standard have "adequate industry experience." These criteria are:

1) the standard is American National Standards Institute (ANSI) accredited
2) the standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner
3) the standard is recognized by key industry stakeholders as the industry standard

For a complete description of the three criteria, see p. 6261 of the NPRM quoted above.

There is no indication in the NPRM that these criteria are to be considered in the alternative or cumulatively. Moreover, there is a confusing subsequent paragraph in the section implying that ANSI accreditation criterion is the sole criterion in determining whether a candidate standard met the requirement of "adequate industry experience." The NPRM asserts on page 6261 that "[t]he standards [for electronic prescribing] should

be vendor neutral and technology independent, and developed by Standards Development Organizations (SDOs) that are accredited by the ANSI."[13]

To the extent the NPRM intends to require that any standard, whether it is a "foundation,"[14] initial or future standard, be ANSI accredited (and/or developed by an SDO that is ANSI accredited) before it can be approved, we oppose such a requirement. We support the position that a candidate standard may be approved in HHS' discretion if it has been implemented by "entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner" and the standard "is recognized by key industry stakeholders as the industry standard," even if it has not been accredited by ANSI or an ANSI accredited organization. Our position is consistent with Congress' express intent in MMA.

**Congress Provided that Standard Setting Responsibility be Retained by HHS**

Congress provided that the process to follow in approving standards for the e-prescribing program include broad criteria and consultation with multiple stakeholders. In doing so, Congress clearly required an expansive process and did not limit it to one in which ANSI accreditation constitutes the sole or final determinant. The basis for Congress' intent to have a broader set of criteria and stakeholders utilized is that there is not an SDO today that has representative participation from all the requisite industry stakeholders. To further clarify this important point, as well as the need for a broader process, MMA specifically requires that all industry stakeholders as enumerated in the statute need to be offered an opportunity to participate in the standard-setting process. MMA appoints NCVHS to play a primary role under the oversight of HHS, which is to retain discretion for the e-prescribing program both for "initial" standards and as the standards evolve under the e-prescribing program. It also identifies the requisite stakeholders with whom NCVHS should consult in developing initial standards as follows: 1) standard setting organizations; 2) practicing physicians; 3) hospitals; 4) pharmacies; 5) practicing pharmacists; 6) pharmacy benefit managers; 7) state boards of pharmacy; 8) state boards of medicine; 9) experts on electronic prescribing; and 10) other appropriate Federal agencies. Section 1860D-4(e)(4)(B). MMA provides for consulting with standard setting organizations, of which NCPDP is one, as well as the other requisite stakeholders, but does not defer overall approval for standards to such an organization.

NCPDP traditionally has enjoyed significant participation from the pharmacy stakeholders. The physician community, which is critical to the success of the e-

[13] We also note that the NPRM (p. 6261) identifies as the first criterion for determining "adequate industry experience" that the "the standard is American National Standards Institute (ANSI) accredited." Note that the September 2, 2004 NCVHS recommendation letter to the Secretary of HHS stated as "guiding principles for selecting standards" (p. 4) that standards "should be vendor neutral and technology independent, preferably be developed by standards development organizations accredited by the American National Standards Institute (ANSI), and have suitable indications of market acceptance." (emphasis added) We assume the NPRM's reference to ANSI includes organizations that are recognized by ANSI, as set forth in the NCVHS recommendation.

[14] The NPRM defines on page 6261 "foundation" standards as standards that do not need to be pilot tested because adequate industry experience with those standards already exists.

prescribing program, is a prime example of a group historically without significant participation in NCPDP. As the e-prescribing program and other emerging e-health initiatives continue, there may be other bodies including standards setting organizations that will organize in the near term with relevant expertise and experience with whom HHS would be well-served to consult for standards approval. In addition, standards may meet the requirements of implementation and stakeholder recognition through means other than an ANSI accreditation process.

The legislative history evidences Congress' intent on the issue of managing the approval of standards. The House passed bill contained language providing that the standards under the e-prescribing program be issued by a standards organization accredited by ANSI.[15] This specific provision, however, was removed during conference, and the final version of the enacted statute did not retain this requirement. This is strong evidence of Congress' preference that HHS receive the input of not only ANSI accredited organizations but all stakeholders, including those not currently represented by such bodies. As a result, the role of NCVHS working in conjunction with HHS to ensure that the process includes all industry stakeholders (identified in MMA) and is conducted in a neutral manner and in a time frame required by MMA, is clearly intended by Congress. For the NPRM to establish requirements that include an ANSI certification as a stand-alone or overarching requirement is contrary to what Congress specified in MMA and risks that standards will not be available within the set time frames or that useful and otherwise valuable standards will be by-passed.

In addition, the ANSI accreditation process is, as acknowledged by the NPRM, a time consuming process. If there is a requirement that such accreditation occur before a standard is adopted, there is the risk of substantial delay, which contradicts the express will of Congress as reflected in the deadlines set forth in MMA and the NPRM's own even more aggressive timeline.

Moreover, if a standard meets the second and third criteria, it can still become ANSI accredited, but HHS does not need to wait for such a final decision. If, for any reason, there is a different or updated standard that comes out of the ANSI accreditation process after adoption of a standard, HHS is free to incorporate such a result in light of its standard setting process. See discussion, *infra*, with regard to updating standards.

Congress intended that the standard setting process be neutral and include consultation with multiple stakeholders in the e-prescribing industry. Defining the process that ANSI accreditation is the sole and final determinant for standards approval (foundation, initial or future) does not reflect this intent, nor the requirements of MMA. We recommend that HHS be the final arbiter of the standard-setting process to ensure that all industry stakeholders are adequately represented, that the process remains neutral and expeditious, that the statutory deadlines are met, and appropriate future standards are promulgated in a timely fashion.

[15] H.R. 1.EH, The "Medicare Prescription Drug and Modernization Act" passed by the House on June 27, 2003. See Section 1860D-3(d)(3)(B)(iii)(III).

**Support for Adoption of RxHub Standards as Foundation Standards Demonstrating Adequate Industry Experience**

As an example, of standards that do not need to go through the ANSI accreditation process, we point to the RxHub standards[16] for formulary/benefits information and for medication history (RxHub standards or standards) to be adopted as foundation standards. The RxHub standards meet criteria two and three set forth in the NPRM, and each of these criteria provide sufficient evidence to satisfy the requirement that there be adequate industry experience. The standards are in wide use today, after being developed in the spirit of other standard-setting organizations giving credence to an open, consensus-building process to multiple stakeholders and working to improve existing standards.

The RxHub standards were developed after the company was formed in 2001 through an open, public workgroup process that it facilitated in several U.S. cities. RxHub sought the consensus of stakeholders including technology vendors, PBMs, health plans, pharmacies, pharmaceutical manufacturers, hospitals and other routing companies. RxHub began with existing standards already being utilized in the industry. RxHub published the proposed standards on the Internet with an open public comment period to obtain feedback from the industry. Production pilots were performed starting in 2002 to test the standards, including applicability to physician office and technology vendor application workflow. RxHub's standards have been modified as experience has been gained. The RxHub standards are in broad use today, including: thirty three partners use the transactions in production applications; five additional partners are certified, ready for production; five additional partners are currently certifying on RxHub transactions; and others are developing to RxHub specifications. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing process further validates the conclusion that the standards meet the two criteria demonstrating adequate industry experience, and hence the RxHub standards should be approved as foundation standards.

RxHub has submitted the standards to NCPDP for accreditation. NCPDP accreditation includes an extensive and time consuming process. The time to achieve NCPDP accreditation for a proposed new standard can take a year or more. The NPRM clearly recognizes that this is a complex, time consuming process. As the standards clearly satisfy criteria two and three evidencing "adequate industry experience," it serves as a prime example of why ANSI certification should not be required for approval as foundation standards. Obviously, the e-prescribing program can nevertheless incorporate standards developed through the ANSI accredited standard setting process.

The RxHub standards meet two of the three criteria outlined in the NPRM for approval as foundation standards, and the NCPDP accreditation process is underway. This functionality meets the requirements of MMA and is critical to the success of the e-prescribing program. If HHS is not prepared to approve these protocols as foundation

[16] As stated *infra*, we endorse these standards, not only because of the process that was followed in their adoption, but based upon their merits.

standards, it should include the protocols in pilot testing to ensure that the tight time frames are met.

**Comments on HHS Provision of Guidance**

The difficulties that HHS has faced in simultaneously setting up a framework for the substantive standards on e-prescribing and establishing the first of those standards argue in favor of HHS providing more guidance in regulating e-prescriptions than can be set forth in any rulemaking. Moreover, they suggest that HHS will have to be prepared to provide that guidance over time, allowing itself flexibility in the development of standards for compliance. Rather than confining itself to the Interim Rule and the Final Rules, HHS should also make provisions for issuing additional guidance to compliance with the e-prescription regulations over time. We recommend that this guidance take the form of a compliance handbook, which HHS can update as necessary. This will give HHS the flexibility crucial to being able to respond effectively to technological changes, regulatory controversies and other developments.

*HHS Should Provide Guidance on Future Standards As Needed*

In raising the issue of the e-prescribing program's future standards, the NPRM suggests that it is best to establish now a predetermined procedure for all standards that may be proposed in the future, and the NPRM appears to conclude that future standards should be approved if they meet the single criterion of ANSI accreditation. As noted above, given the need for broader consensus building, neutrality and participation by all industry stakeholders, we are concerned about the blanket imposition of an ANSI accredited standard setting process as the sole requirement for approval. We also believe, however, that it is premature to set the technical standards in stone. So much remains uncertain, including how readily different stakeholders will accept individual standards (which may depend in part on how involved they are in the standards-setting process) and how effective federal preemption will be (or will be allowed to be) in making any accepted standards uniform nationwide. It seems unnecessarily ambitious to suggest that a permanent framework for standards setting can be established at this point, before the marketplace has had a chance to operate and issues have had a chance to surface.

We would recommend, instead, that HHS take the opportunity in the Interim Rule to set up a flexible guidance process, designed specifically to prevent the e-prescription standards-setting rules from becoming prematurely rigid. HHS already is empowered to issue guidance from time to time as necessary as it gains experience with the issues and oversees the e-prescribing program's implementation. As needs for future or evolving standards become clear, HHS can use this guidance to address matters related to the standards that remain within the scope of MMA and impact the maintenance of "backwards compatibility" among e-prescribing program participants. There will be ample time for HHS to issue a final formula for approving future standards when and if the need for such a formula is clearly identified, which we expect will be some time after the foundation and remaining initial standards are successfully implemented.

*HHS can Enhance Its Rule-Based Regulatory Authority*
*Through Creation of an Effective Guidance Structure*

While it may seem that HHS would be incapable of establishing the same certainty as to the procedures to be adopted with respect to e-prescriptions by guidance as it could by rulemaking, in fact that is not necessarily the case. Other informal guidance structures established by federal agencies are fully the equivalent of formal rules in the effectiveness with which they shape the compliance activities of persons subject to them. For example, the Department of Housing and Urban Development's Federal Housing Administration ("FHA") not only has issued regulations that set forth the framework of standards under which private parties such as approved lenders may make mortgage loans and obtain FHA insurance for those loans, but has also provided in those regulations that it would issue a variety of handbooks that contain much more specific guidance for industry participants. These officially issued handbooks effectively define what constitute permissible practices with respect to FHA-insured mortgages.[17] This is particularly of interest in the case of the Interim Rule under the MMA because like the MMA, the National Housing Act under which the FHA regulation has been promulgated by HUD does not specify that the FHA should provide regulatory guidance in this manner. HHS has the authority to implement the MMA in this way if it should determine that this would be the most effective method of providing practical guidance in the implementation of electronic prescription provisions of the MMA. We believe that the FHA has found that this mechanism has given it flexibility to adjust rapidly to changing market conditions and advances in technology. The existence of this mechanism allows FHA to issue guidance to the market without going through a slow notice and comment rulemaking process so long as the guidance remains within the broader regulatory framework. Finally, we note that the markets and the courts have accepted this guidance as legally binding, and even preemptive of state law to the same extent as the statute and the regulations.

The essential step for HHS to take now, in order to enable such a structure, is to authorize it in the Interim Rule itself. This should be done explicitly, perhaps by inserting into the Interim Rule a sentence along the lines of "The Secretary shall publish guidelines for electronic prescription procedures, which shall be provided to all participants in this program." That having been done, HHS can in due course determine the appropriate structure for such guidance – whether as a continuously updated question and answer document, discrete letters in response to questions submitted by industry and consumers, or a connected handbook on the order of HUD's guides. Having the ability to produce such guidance, in whatever form, means that HHS will not have to resolve all questions of process before promulgating the Interim Rule, and will not have to resolve all substantive questions before promulgating the Final Rules.

[17] See, e.g., 24 C.F.R. 203.5(c) (Direct Endorsement Program) ("The Secretary shall publish guidelines for Direct Endorsement underwriting procedures in a handbook, which shall be provided to mortgagees . . ..")

**PROPOSED FOUNDATION STANDARDS**

BACKGROUND, G. Electronic Prescription Drug Program and

BACKGROUND, H. Summary of Status of Standards for an Electronic Prescription Drug Program

Also relates to: PROVISIONS OF THE PROPOSED REGULATION, E. Proposed Standards]

*Electronic Prescription Drug Program*

*NPRM, p. 6263. "Adoption of standards for formulary representation and medication history would clearly enhance e-prescribing capabilities under Part D. Such standards would make it possible for the prescriber to obtain information on the patient's benefits, including the formulary status of drugs that the physician is considering prescribing, as well as information on medications the patient is already taking including those prescribed by other providers. Significant quality improvement and cost savings could result from the use of formulary and medication history standards.*

*The NCVHS noted that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange…*

*The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocols as a basis, and indicated its belief that this appeared possible in time to adopt the standards as a foundation standards.*

*We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards…*

*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging…, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards…"*

*Summary of Status of Standards for an Electronic Prescription Drug Program*

*NPRM, p. 6264. "We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards... In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

- *The…NCPDP SCRIPT Standard.*
- *The…ASC X12N 270/2711 Transaction.*

• *The…NCPDP Telecommunication Standard."*

**Eligibility Inquiry and Response**

We support the designation of the ASC X12N 270/271 transaction set as a "foundation standard" for purposes of the eligibility inquiry and response functionality required under the e-prescribing program. The candidate standard meets the requisite criteria for approval as a foundation standard. Sufficient evidence exists to establish "adequate industry experience" with ASC X12N 270/271. This transaction is broadly used among and interoperable with multiple parties to verify patients' eligibility for coverage in the context of e-prescribing. Importantly, this standard transaction has already been implemented to be in compliance with the HIPAA privacy requirements for communications between the prescriber and PBMs/payors. An additional integral capability that this standard transaction supports is coordination of benefits by notifying the prescriber that a patient is enrolled in more than one health benefit for which there is coverage.

After review of the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims (E1 Message) in the context of the statute's requirements for "adequate industry experience," we do not support designation of the E1 Message as a foundation standard at this time. In our research, we cannot conclude that there is widespread or time-tested experience among the required participants in the e-prescribing program. The E1 Message is limited to verification of a patient's cardholder status under a particular benefit plan and does not include the functionality to manage industry-critical coordination of benefits requests.

It is our recommendation that the E1 Message be tested further in a pilot environment and modified as warranted prior to consideration as a standard for eligibility transactions.

We also make reference to the fact that eligibility and response transactions can be used with information source organizations other than health plans (i.e., for transactions that are not standard transactions as defined by HIPAA). *See, e.g.,* ASC X12N 270/271 – Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, Page 11, Section 1.3.1. We therefore request that CMS define the two eligibility transactions for which it proposes standards as "eligibility inquiries and responses submitted and received by pharmacies" and "eligibility inquiries and responses submitted and received by prescribers." This would not change the fact that a provider that is not otherwise a covered entity under HIPAA would become a covered entity if it conducts an e-prescribing transaction that is also a HIPAA standard transaction, such as exchanging 270/271 eligibility and response transactions with a health plan.

**Drug Order for New Prescriptions, Renewals, Cancellations, and Change Orders**

We support designation as a foundation standard the most current version of the NCPDP SCRIPT standard to conduct transactions between prescribers and dispensers as to new prescriptions, prescription renewals, cancellations, and changes between prescribers and dispensers. We understand that this transaction standard also contains several additional messaging capabilities within it. We recommend that there be further experience with the additional messaging capabilities (other than the functionality above) before the additional messaging capabilities are determined to be standards under the e-prescribing program.

**Formulary/Benefit Coverage Information and Medication History**

We support the designation as foundation standards of the formulary and benefits coverage information standard and the medication history standards developed by RxHub (RxHub standards). We are strongly of the view that there is sufficient evidence for HHS to determine that there exists "adequate industry experience" with the RxHub standards for them to be approved without delay as foundation standards.[18]

The RxHub standards are the most utilized transaction formats in the marketplace today for the MMA-required functions of formulary and benefit coverage information as well as medication history. The e-prescribing industry has ample experience with the standards for them to be named as foundation standards. In great part this is attributable to the industry stakeholders themselves offering comment through a public workgroup process as to what would best serve them from their individual perspectives and advance the interests of industry "interoperability" as a whole. These collaborative industry efforts resulted in the development of the RxHub standards in use today. After they were developed and tested, the standards were further scrutinized in production environments with multiple participants to move beyond the testing platform into a full operational environment upon which prescribers and payors can and do rely.[19] More specifically, the standards are used by most of the e-prescribing solution providers and each of the three largest PBMs (managing the pharmacy benefits of over 150 million people), which has been the case for several years.

NCVHS recognized the current usage of the RxHub standards among prescribers and payors in the marketplace, including the stakeholders who will participate under the e-prescribing program. Testimony during NCVHS's hearings on e-prescribing standards from various stakeholders in the e-prescribing industry demonstrates the breadth and duration of industry experience with the RxHub standards. It is important to note that there are no alternative standards for this functionality today. As a result of this comprehensive review of candidate standards in the context of MMA requirements,

[18] We also refer to the discussion, *supra*, regarding the standard-setting process, particularly the criteria on page 6261 of the NPRM for determining "adequate industry experience."

[19] For additional information about the development of the RxHub standards, see the discussion, *supra*, regarding the standard-setting process.

NCVHS recommended to the Secretary that HHS actively support using the standards as the basis for swift deployment of a standard to address the functionality of formulary/benefits coverage information and medication history.

It is our understanding that RxHub has submitted the standards to NCPDP. Although NCPDP has and continues to make contributions to participating members of the industry, it does not include all of the requisite stakeholders under MMA. The RxHub standards were made open for comment from all interested parties and have been adopted by a broad group of interested stakeholders, including PBMs/payors, prescribers and the technology vendors that interface with them. In light of the process that was followed by RxHub, the current use within the industry, and that there are no alternative standards at present, there is no reason to subject the standards to further review or testing. Moreover, as previously discussed, we do not believe that ANSI accreditation should be a prerequisite before the Secretary can approve a standard. See the discussion, *supra,* regarding ANSI accreditation.

Since there is "adequate industry experience" with the RxHub standards, they should be adopted as foundation standards. If, however, HHS is not prepared to act accordingly, it should include the standards in pilot testing to ensure timely adoption. Approval of the RxHub standards as foundation standards is vital to the successful implementation of a nationwide e-prescribing program.

**DEFINITIONS OF "ELECTRONIC MEDIA" AND "E-PRESCRIBING"**

BACKGROUND, A. Statutory Basis

PROVISIONS, B. Proposed Definitions

*NPRM, page 6257. "Electronic media is defined under HIPAA to include both electronic storage media and transmission media… However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards."*

The HIPAA definition of "electronic prescribing" at 45 CFR 160.103 reads as follows:

"Electronic media means:

(1) Electronic storage media, including memory devices in computers (hard drives), and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
(2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private

networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission."

The definition of "e-prescribing" on page 6265 and 6273 of the NPRM includes the term "electronic media" and reads as follows:

> "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network."

Subject to the caveat regarding electronic faxes discussed below, we support the use of the definition of "electronic media" to determine when prescribers and dispensers are electronically transmitting prescription information, and as a result of such activity, should be required to comply with the e-prescribing standards.

We would note, however, that we interpret the definition of "electronic media" to include electronic faxes, which we are advised are currently utilized by some e-prescribing systems to transmit prescribing information. Electronic faxes are computer generated files transmitted by fax that never exist in non-electronic form and thus do not fall within the exception set forth in the last sentence of HIPAA's definition of "electronic media." Because electronic faxes do not comply with the NCPDP SCRIPT foundation standard, they could not be used to e-prescribe under the NPRM as currently drafted.

Unless HHS is comfortable that e-prescribing systems currently utilizing electronic faxes should undergo the additional expense and training required to move from fax to electronic data interchange prior to January 1, 2006, the Department may want to include a transition period in the Interim Rule during which those systems could continue to utilize electronic faxes for the electronic transmission of prescribing information.

**PROVIDER AND DISPENSER IDENTIFIERS**

BACKGROUND, G. Electronic Prescription Drug Program

*NPRM, page 6262. "HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. . . . Accelerated NPI usage for e-prescribing may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. . . . We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions. . . . and alternatives to the NPI, particularly in the short term. . . . NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers*

*and the NCPDP HCIdea for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), . . . in the event the NPI is not available for use, and we invite public comment on this as well."*

We concur with the concerns raised in the NPRM that may make it difficult for HHS to accelerate the use of National Provider Numbers (NPIs) for the e-prescribing program by January 1, 2006 (*i.e.*, insufficient capacity to issue NPIs to all covered provides by that date and well as "unforeseen system or budget concerns"). There are several moving parts that need to be in place and operational on January 1, 2006 to assure the success of the e-prescribing program for covered Part D drugs and there is little logic to accelerating the use of NPIs when existing identifiers are in place to facilitate e-prescribing.

For dispensers, the NCPDP Provider Identifier Number suggested in the NPRM as an interim identifier is in wide use. For prescribers, the suggested NCPDP HCIdea identifier as a possible identifier is not widely adopted.

Testimony before the NCVHS by a variety of groups involved in e-prescribing did not indicate any concerns related to the current use of identifiers by dispensers or prescribers. Since, as noted in the NPRM, "the MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers or dispensers in e-prescribing transactions," it is not necessary that HHS approve specific identifiers for use by the January 1, 2006 effective date.

We recommend that the Interim Rule affirm that HHS intends to require the use of approved identifiers for use by entities participating in the e-prescribing program in the Final Rule upon completion of the pilot tests and that it authorizes the use of current identifiers until the Final Rule is issued.

The NPRM notes that the NPI may be the "preferred option" as an identifier "because it is standard that many entities will be required to use under HIPAA." That may well be the case and pilot testing will indicate whether the NPI, which is designed for the processing of claims can be successfully modified to meet the additional requirements regarding the identification of prescribers (*i.e.*, identification of the individual prescriber for security validation and medication history and other purposes as well as identification of the specific location where the prescriber provides for the patient, etc.).

**STARK EXCEPTION AND ANTI-KICKBACK SAFE HARBOR**

BACKGROUND, A. Statutory Basis, 3. Anti-kickback Safe Harbor and Stark Exception

IMPACT ANALYSIS, B. Impact on Health Plans/PBMs and C. Impact On Prescribers

*Anti-kickback Statute Safe Harbor and Stark Exception*

*NPRM, p. 6259. "Section 1860D-4(e)(6) of [MMA] requires the Secretary to promulgate regulations that provide a "safe harbor under the anti-kickback statute . . . and an 'exception' under the physician self-referral statute for certain nonmonetary remuneration related to e-prescribing information technology items and services.*

. . .

*"We will propose the new Stark exception for electronic prescribing in a separate rulemaking to be published in the near future. The new safe harbor under the anti-kickback statute will be proposed by the Office of the Inspector General."*

*Impact on Health Plans/PBMs*

*NPRM, p. 6269. "We expect many plans to offer [financial incentives and technical assistance] to prescribers to offset initial costs of installing the hardware and software, thereby encouraging the adoption of e-prescribing."*

. . .

*"Health plans have a substantial incentive to subsidize the cost of physician's adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance. Thus, it is likely that the net effects on plans would be positive rather than negative."*

*Impact on Prescribers*

*NPRM, p. 6270. "We expect e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, but the magnitude and timing of savings will have to be demonstrated to many prescribers to induce them to make the 'up front' investment in new systems."*

. . .

*"One of the barriers to early adopting of e-prescribing by prescribers is the cost of buying and installing a system. . . . Since these costs may be defrayed by the incentives that are being offered, or may be offered, we expect a steady increase in the number of electronic prescribers."*

Participation in the e-prescribing program by prescribers is voluntary. Congress recognized at Section 1860D-4(e)(6) of the MMA that prescribers would need incentives to participate in a voluntary program and that the current safe harbors available under the anti-kickback statute and the existing Stark exceptions were too restrictive to provide the necessary incentives.

While the availability of incentives is important to encourage prescribers who do not currently e-prescribe to install an e-prescribing system, it is crucial to those prescribers, of which there are many, who installed e-prescribing systems in the past only to walk away when the systems did not produce anticipated results. The need for incentives would become more pronounced if the e-prescribing system prescribers are being asked to install were to be confined to electronic prescriptions of covered Part D drugs for Part D eligible individuals enrolled in Part D plans.[20]

The NPRM at pages 6270 and 6271 requests information that will assist in assessing the "costs [to prescribers] of implementing" e-prescribing systems. We agree with the NPRM that key factors in calculating "the overall costs of buying and installing [e-prescribing] systems" include the "hardware and software" as well as the need to (i) change business practices of prescribers offices, (ii) changing record systems from paper to electronic and (iii) training staff. Even with these factors, costs can increase if the factors are broadly interpreted. By way of example, does the NPRM contemplate the cost of "changing record systems from paper to electronic" to be limited to the cost of moving to electronic records from the point the system becomes effective, or does it also include the cost of converting a patient's existing medication history from paper to electronic?

We concur with NPRM's expectation at page 6269 that health plans, including PDPs and MA-PDs, will want to offer to prescribers "financial incentives and technical assistance" beyond that currently permitted under the Stark exceptions and anti-kickback safe harbors to "encourage the adoption of e-prescribing."

We recommend that, in developing the Stark exception and the anti-kickback safe harbor required under Section 1860D-4(e)(6), HHS should provide a broad interpretation of incentives that would be made available for use by health plans to encourage e-prescribing including the contribution of the equipment (hardware, software, etc) necessary to an e-prescribing system as well as reimbursement for costs incurred in training staff to operate the system and hiring staff to convert paper records to electronic together with incentives for rewarding prescribers for quality of performance achieved through the use of e-prescribing.

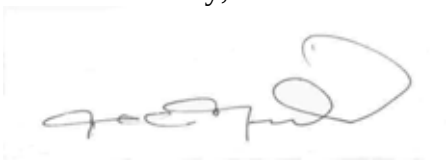
* * *

[20] *See* the analysis, *infra*, that the narrow scope of preemption proposed in the NPRM would leave a number of conflicting state e-prescribing laws and regulations in place with the result that prescribers would be unable to use the Part D e-prescribing program for their non-Part D eligible patients without violating state laws.

The RxBC appreciates the opportunity to comment on the NPRM. We look to working with the Department as the process moves forward and to reaching our mutual goals of moving to a health care system that not only improves the quality of care, but reduces the cost of health care by harnessing the benefits technology can bring to the health care sector.

With best regards, I am

Sincerely,



Anne C. Canfield
Executive Director

## ATTACHMENT A

# M E M O R A N D U M

November 23, 2004

**The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 Preempts State Laws and Regulations that Restrict or Impede a National Electronic Prescribing System**

## EXECUTIVE SUMMARY

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") creates a new outpatient prescription drug benefit for Medicare beneficiaries. As part of this benefit, Congress mandated the creation of a national electronic prescription and health care data access system (referred to collectively in this memorandum as "e-prescribing"). This system includes not only the electronic transmission of a prescription from the prescriber's office to the pharmacy, but also provides for electronic transmission of the patient's medication history, drug to drug interactions, and the availability of lower cost alternatives. Congress recognized that e-prescribing can reduce medical errors and improve efficiency in the health care system and directed the Department of Health and Human Services ("HHS") to develop uniform national standards for e-prescribing in order to promote its adoption.

Because of the importance Congress placed on the need to foster e-prescribing, it expressly determined in section 1860D-4(e)(5) of the MMA that

> The standards promulgated under this subsection shall supersede any State law or regulation that—
>
> (A) is contrary to the standards or restricts the ability to carry out this part; and
>
> (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

This memorandum examines, among other points, whether the "and" between subparagraphs (A) and (B) means that a state law or regulation must offend both provisions before it is preempted. Such a reading would negate both the goals Congress sought to achieve and render superfluous one of the two provisions. Thus, subparagraphs (A) and (B) must be read to have independent meaning.

The MMA both expressly and impliedly preempts state law. The express statutory preemption language is broad; words such as "pertains," "relates," and "refers" are words of

broad construction, and the Supreme Court has repeatedly emphasized that the use of a "related to" preemption clause signals a "clearly expansive" preemptive intent. *See Rush*, 536 U.S. at 365-66 (ERISA preemption clause which uses "relate to" language "seems . . . to preempt everything"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992) (preemption provision using term "relating to" must be given broad reading). *See also Egelhoff v. Egelhoff*, 32 U.S. 141, 146 (2001); *Barnett Bank of Marion County, NA v. Nelson*, 517 U.S. 25, 38 (1996).

In addition, the language of the e-prescribing section as a whole demonstrates that Congress preempted state law with regard to all covered part D drugs. Section 1860D-4(e)(1) of the MMA explicitly references "covered part D drugs *prescribed for part D eligible individuals* . . ." (emphasis added). In contrast, section 1860D-4(e)(5)(B), the preemption provision at issue here, makes reference merely to "covered part D drugs under this part," which is simply a broad list of commonly used prescription products. It does not limit its reach to those drugs *prescribed for part D eligible individuals*, though Congress clearly knew how to do that if it wished to. Moreover, section 1860D-4(e)(3)(C)(i) states that the HHS standards shall "not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists." The burden of having separate and conflicting systems for prescribing to patients covered by Medicare would contradict this requirement. This is so regardless of how one reads subparagraphs (A) and (B).

Even in the absence of an express preemption provision, the MMA would impliedly preempt state law because to the extent state laws and regulations either vary dramatically with each other and the to-be-adopted federal standards, or simply do not address issues addressed by the federal standards, state law is an obstacle to achieving what Congress set out to achieve. The existence of varying and conflicting state laws makes a uniform e-prescribing system – the goal of the MMA – unattainable. Accordingly, state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Boggs v. Boggs*, 520 U.S. 833, 844 (1997) (quoting *Gade v. Nat'l Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 98 (1992)).

## I. Introduction

While the federal government has been involved in purchasing drugs through the military and veterans' health care systems, this is the first program that will ultimately reach all Americans when they qualify for Medicare.[1]

Evidencing Congress's considerable interest in the scope and parameters of such a program, the MMA contains a variety of provisions concerning healthcare information technology. Among these is a comprehensive electronic prescribing program for Medicare beneficiaries, a program which Congress envisions as encompassing significantly more than simply how to transmit a prescription electronically:

[1] The Medicare Catastrophic Coverage Act of 1988 created a prescription drug benefit for Medicare beneficiaries. The act was repealed in 1989, however.

> An electronic prescription drug program shall provide for the electronic transmittal to the prescribing health care professional and to the dispensing pharmacy and pharmacist of the prescription and information on eligibility and benefits (including the drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) and of the following information with respect to the prescribing and dispensing of a covered part D drug:
>
> > (i) Information on the drug being prescribed or dispensed and other drugs listed on the medication history, including information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments.
> > (ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed.

§ 1860D-4(e)(2)(A).

> In addition, HHS is directed to:
>
> provide for the electronic transmittal in a manner similar to the manner under subparagraph (A) [quoted above] of information that relates to the medical history concerning the individual and related to a covered part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved.

§ 1860D-4(e)(2)(B).

The breadth of the national e-prescribing standards is a logical corollary to Congress' goal that a uniform national standards will "serve as a vehicle to reduce medical errors and improve efficiencies in the health care system . . . ." House Conf. Rept. 108-391 at 28. (Appendix A, attached, contains a detailed summary of the provisions relating to electronic prescribing contained in the MMA.) The Centers for Medicare and Medicaid Services has also recognized this dual potential of an effective e-prescribing system. *See* Centers for Medicare and Medicaid Services, Proposed Rule, Medicare Program; Medicare Prescription Drug Benefit, 69 Fed. Reg. 46,631, 46,672 (Aug. 3, 2004). While participation in the program is not mandatory, the standards are mandatory if any electronic prescription is used.

The need to improve patient safety is real. A National Academy of Sciences\Institute of Medicine report estimates that medical errors cost the nation approximately $37.6 billion each year, about $17 billion of which is associated with preventable errors. TO ERR IS HUMAN: BUILDING A BETTER HEALTH CARE SYSTEM 23 (1999), *available at* http://books.nap.edu/html/to_err_is_human/Ch2.PDF). Medication errors are caused by a wide variety of factors: poor communication; ambiguities in product names, directions for use, medical abbreviations or writing; poor procedures or techniques; or patient misuse because of poor understanding of the directions for use of the product. U.S. Food and Drug Administration, Center for Drug Evaluation and Research, "Medication Errors," *at* http://www.fda.gov/cder/handbook/mederror.htm (last visited Oct. 1, 2004).

In order to ensure that the standards promulgated by HHS are successful, the MMA tasks the National Committee on Vital and Health Statistics (NCVHS), a public advisory body to the

Secretary of HHS, with the job of recommending e-prescribing standards to HHS after consultations with a variety of industry and government stakeholders. NCVHS's initial recommendations to HHS identify technical standards on which e-prescribing software and systems either have been built or can be built. NCVHS noted there that, "Standards for e-prescribing must not only meet the requirements of MMA but must also be compatible with all other standards that are becoming part of the National Health Information Infrastructure (NHII). This includes standards developed under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and the Consolidated Health Informatics Initiative (CHI)." NCVHS letter to Tommy G. Thompson at 1 (Sept. 2, 2004) *available at* http://www.ncvhs.hhs.gov/040902lt2.htm. It is important to recognize, as NCVHS has, that it is not writing on a clean slate, nor did Congress direct it to do so. To the extent possible, it has proposed using existing, open architecture standards which do not provide a commercial advantage to any particular company.

To establish a uniform national system that improves patient safety and increases efficiency while not imposing an undue burden on the health care system, Congress determined that federal law shall rule in this area: "The [e-prescribing] standards . . . shall supercede any state law or regulation that (A) is contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part." § 1860D-4(e)(5).

This provision must be read broadly, as a call for federal occupation of the entire e-prescribing field with respect to covered part D drugs, or it will be ineffective in addressing the goals that Congress made explicit in the statute. A restrictive reading of the provision will add conflict and confusion to the current landscape of e-prescribing, which is already littered with varied and inadequate state laws.

## II. Only National E-Prescribing Standards Can Solve the Problems Congress Sought to Address in the MMA

Significant state law barriers stand in way of building an effective e-prescribing system. Specific state laws and regulations that have hindered the adoption of electronic prescribing include:

- Requirements of special patient consent to the use of electronic prescribing. *See, e.g.*, Nev. Admin. Code ch. 639, § 7105.2(b) (2001); Fla. Admin. Code Ann. r. 64B16-28.130 (2001).

- Prohibitions on intermediaries facilitating transmission of prescription information (e.g., anti-depot rules). *See, e.g.*, Del. Admin. Code tit. 24, § 2500.5.10.1.1 (2001); Ohio Admin. Code § 47-29-5-10(A) (2001).

- Restrictions on prescription content and format, especially those drafted with only paper prescriptions in mind. *See, e.g.*, N.C. Admin. Code tit. 21, r. 46.1813(b)(2), (3); N.C. Gen. Stat. § 90-85.28(b) (2001); N.J. Rev. Stat. § 45:14-14.2 (2001); N.J. Rev. Stat. § 24:6E-7 (2001);

- Absence of an objective achievable standard on which pharmacists can rely for authenticating the source of electronic prescriptions. *See, e.g.*, Mich. Admin. Code. r. 338.3162a(3)(b) (2001); Tex. Health & Safety Code Ann. § 483.021(a); N.M. Admin. Code tit. 16 § 19.6.23(F) (2004); N.Y. Comp. Codes R. & Regs. tit. 8, § 63.6(a)(7) (2004).

- Varying state privacy laws and restrictions (*e.g.*, requirements that certain drugs be filtered out of medication histories unless the source of the medication history obtains the patient's consent). *See, e.g.*, Mass. Regs. tit. 247, § 9.01(19) (2001); Tex. Occ. Code Ann. § 562.015 (2001).

Accordingly, in some states e-prescribing is, if not prohibited, difficult and cumbersome, as noted above. Even where e-prescribing is possible, different formats and requirements (e.g., with respect to authentication and prescription format) make a uniform e-prescribing system unattainable. In addition to the legal impediments to e-prescribing, the lack of uniform national standards also means that software vendors must design multiple systems, adding both to the expense of the systems and the risk that different systems will not interface readily. The risk of standards that do not interface is that physicians and pharmacies will be hesitant to purchase multiple systems and thus avoid e-prescribing altogether. It is against this patchwork of state regulation – and omission – that Congress sought to provide uniform national standards for e-prescribing.

## III. A Broad Interpretation of the MMA's E-Prescribing Provisions Is Mandated by the Plain Language of the Statute and Judicial Precedent

### A. The Plain Language of the MMA Expressly Preempts State Law

In directing the Secretary of HHS to adopt national standards under the MMA's electronic prescribing program, Congress expressly determined that these standards would broadly preempt state law. The e-prescription preemption provision, to be codified at 42 U.S.C. § 1395w-104(e)(5), provides that:

> The standards promulgated under this subsection shall supersede any State law or regulation that—
>
> (A) is contrary to the standards or restricts the ability to carry out this part; and
>
> (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

§ 1860D-4(e)(5).

The concept of federal preemption of state laws is rooted in the U.S. Constitution. "A fundamental principle of the Constitution is that Congress has the power to preempt state law." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372 (2000). Federal preemption of state laws or regulations can be either explicit or implicit: preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977).

"It is well-established that within Constitutional limits Congress may preempt state authority by so stating in express terms." *Pac. Gas & Elec. Co. v. State Energy Res. Conservation & Dev. Comm'n*, 461 U.S. 190, 203 (1983); *see Jones*, 430 U.S. at 525. Where a statute contains an express preemption provision, the "'task of statutory construction must in the first instance focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Sprietsma v. Mercury Marine*, 537 U.S. 51, 62-63 (2002) (quoting *CSX Transp., Inc. v. Easterwood*, 507 U.S. 658, 664 (1993)).

The MMA expressly preempts state law. The express statutory language of subparagraph (A) is unambiguous: the federal standards "*shall supercede"* state law or regulation that is contrary to the standards or restricts the ability to carry out "this part." As used in this sentence, "part" means all of the provisions of the MMA which create the prescription drug benefit for Medicare beneficiaries. *See* Sec. 101(a)(2) of the MMA. This language not only preempts state laws that are contrary to the standards adopted by the Secretary pertaining to e-prescribing, but any state law that restricts the ability to carry out any provision of the MMA regarding the part D prescription drug benefit.

Similarly, the statutory language of subparagraph (B) is equally broad. It preempts any state law or regulation that "pertains" to the electronic transmission of medication history and of specified information with respect to covered part D drugs under this part. Words such as "pertains," "relates," and "refers" are words of broad construction, and the Supreme Court has repeatedly emphasized that the use of a "related to" preemption clause signals a "clearly expansive" preemptive intent. *See Rush*, 536 U.S. at 365-66 (ERISA preemption clause which uses "relate to" language "seems . . . to preempt everything"); *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383-84 (1992) (preemption provision using term "relating to" must be given broad reading). *See also Egelhoff v. Egelhoff*, 532 U.S. 141, 146 (2001); *Barnett Bank of Marion County, NA v. Nelson*, 517 U.S. 25, 38 (1996).

The breadth of the preemption provision must be read against the breadth of the components of the national electronic prescribing program which Congress has mandated. *See* page 3, *supra.* Based upon the strong "plain wording" of each clause, the preemption provision should be read so that state laws and regulations that fall under (A) are preempted and state laws and regulations that fall under (B) are preempted.

1. The Scope of Subparagraph (A)

Subparagraph (A) preempts any state law or regulation which "is contrary to the standards or restricts the ability to carry out this part…." Were this the only preemption language in the statute, there would be little disagreement that Congress expressly preempted a

wide range of state laws and regulations. However, Congress used “and” to join subparagraphs (A) and (B), thus raising the question of whether (A) and (B) are independent preemption provisions.

The fact that Congress used the word "and" to connect subparagraphs (A) and (B) cannot be interpreted in a manner in which subparagraph (B) limits subparagraph (A) without conflicting directly with the broad preemptive language employed by Congress. Courts have held that a “statute’s use of disjunctive or conjunctive language is not always determinative.” *United States v. Bonilla-Montenegro*, 331 F.3d 1047, 1051 (9th Cir. 2003). Rather, courts “give effect to the plain, common-sense meaning of the enactment without resorting to an interpretation that def[ies] common sense.” *Id*. (internal quotation marks omitted). *Cf. Reiter v. Sonotone Corp.*, 442 U.S. 330, 339 (1979) (“Canons of construction ordinarily suggest that terms connected by a disjunctive be given separate meanings, *unless the context dictates otherwise*.”) (emphasis added). Here, the “context dictates otherwise” because only that interpretation gives meaning to both (A) and (B).

A requirement that a state law or regulation offend both (A) and (B) before it is preempted would render one of the two provisions redundant. It would also mean that a state law which directly conflicted with the national standards, but did not pertain to the transmission of the information identified in (B) would not be preempted (unless by implication, *see infra*). Likewise, it would mean that a state law which did not directly “pertain to” the transmission of information, yet which nonetheless “restricted” the government’s ability to carry out the standards would not be expressly preempted. Such an interpretation would nullify (A), a result the courts have rejected. “The rule against superfluities complements the principle that courts are to interpret the words of a statute in context. See 2A N. Singer, Statutes and Statutory Construction §46.06, pp. 181.186 (rev. 6th ed. 2000) (‘A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .’ (footnotes omitted)).” *Hibbs v. Winn*, 540 U.S. ___ (June 14, 2004). Congress' clear intent to preempt state laws that are contrary to the standards, or that restrict the ability to carry out the Medicare outpatient drug benefit, should be fully effectuated in its own right.

2. The Scope of Subparagraph (B)

The preemptive effect of (B) is aimed squarely at any state law or regulation which “pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.” Thus, any state law or regulation which broadly pertains to the listed subjects is preempted.

The first issue with regard to (B) is whether the phrase "with respect to covered part D drugs under this part" modifies all of (B) or only modifies the immediately preceding phrase, "information on eligibility, benefits, and prescriptions." The plain language makes clear that the latter interpretation is what Congress intended. Use of the word "of" in front of "medication history" and again in front of "information on eligibility" indicates that there are two categories of information and the reference to covered part D drugs modifies only the second category.

The next issue is whether the phrase "covered outpatient drugs under this part" refers to all outpatient drugs that are eligible for compensation under part D or to only those drugs that are actually compensated under part D. The context of the MMA provisions on e-prescribing make clear that the former is the correct interpretation.

For example, section 1860D-4(e)(1) of the MMA explicitly references "covered part D drugs *prescribed for part D eligible individuals . . .*" (emphasis added). In contrast, section 1860D-4(e)(5)(B), the preemption provision discussed here, makes reference merely to "covered part D drugs under this part," which is simply a broad list of commonly used prescription products. It does not limit its reach to those drugs *prescribed for part D eligible individuals*, though Congress clearly knew how to do that if it wished to.

The Congressional goal of improving patient safety would be undermined if the other elements of the e-prescribing package – medication history, eligibility and benefits – were limited to part D drugs *paid for* under this part. A drug which a beneficiary bought and paid for without reimbursement by Medicare or that was reimbursed by another payor would be as relevant a part of the patient's medical history as drugs paid for under this part. In addition, even as to eligibility, benefits and prescriptions, Congress clearly wanted to include information regarding dual coverage (where another payor might be obligated to pay for the drug) or those instances in which the Medicare benefit requires the patient to pay out of pocket. This information is of great importance to the provider, patient, and the proper administration of the part D benefit. In addition, the plain language of the e-prescription section as a whole demonstrates that Congress preempted state law with regard to all part D drugs. Section 1860D-4(e)(3)(C)(i) states that the HHS standards shall "not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and pharmacists." But the burden of having separate and conflicting systems for prescribing for patients covered by Medicare would frustrate this requirement, just as having conflicting state laws would.

This interpretation is consistent with the plain language of subparagraph (B) as well as court decisions cited, *supra*.[2]

3. The Legislative History Confirms that Congress Intended to Give Effect to (A) and (B)

The legislative history further confirms that Congress intended a broad interpretation of the express preemptive effect of the MMA e-prescribing standards. *See Oklahoma v. New Mexico,* 501 U.S. 221, 234 n.5 (1991)(courts consult legislative history when a statute's meaning is ambiguous). The House Conference Report states simply and without qualification: "The electronic prescribing standards shall supercede any contrary state laws." House Conf. Rept. 108-391, p. 456.

The broad sweep of the preemption provision is necessary if the Congressional goals of reducing medication errors and more efficiently delivering services is to be achieved. Subparagraph (B) reaches those state laws and regulations which "pertain" to the specific subject matter of the specified standards to be adopted; that is, any state law or regulation on the same

[2] This is the case regardless of whether one reads subparagraphs (A) and (B) as disjunctive or conjunctive.

subject. Subparagraph (A) sweeps even more broadly: it recognizes that there may be state laws and regulations which are "contrary to" or which "restrict the ability" to carry out the goals of the national standards. They, too, are preempted. Thus, a general state law or regulation (such as one dealing with electronic payment of health insurance claims for prescription drugs) which "restricts the ability to carry out this part" is preempted even if it does not pertain to the transmission of information specified in (B). This reading of the preemption provision accords with the canon that courts "give effect to the plain, common-sense meaning of the enactment without resorting to an interpretation that def[ies] common sense." *Bonilla-Montenegro*, 331 F.3d at 1051 (internal quotation marks omitted).

Finally, under the rules of statutory construction cited *infra*, an interpretation that the language of (B) limited (A) would not change the broad scope of preemption with regard to the e-prescribing provisions of the MMA. As noted above, an electronic prescription as defined in the MMA includes more than the transmission of the prescription from the prescriber to the pharmacy, but also includes information regarding eligibility, benefits, medication history and drug to drug interactions. The standards and the ability to carry out the part D program with regard to an electronic prescription system all pertain to the content and scope of information as well as to standards pertaining to the actual electronic transmission of information. Congress' use of the term "pertaining" preempts "everything," *see Rush*, 536 U.S. at 365-66, which in this case would include the information content and the actual electronic transmission of the information. Accordingly, state laws and regulations which conflict with the standards relating to the e-prescribing system with regard to the part D prescription drug benefit would also be preempted to the extent of the conflict. The result, at least in the area of e-prescribing, of reading (B) as conjunctive with (A) is the same as a disjunctive reading.

### B. The Law of Implied Preemption Would Preempt State Law Relating to the E-prescribing System Had Congress Not Chosen To Do So Expressly

Established principles of implied preemption support a broad view of the scope of preemption Congress adopted. Even without an express preemption provision, the Supreme Court has found that "state law must yield to a congressional Act in at least two circumstances." *Crosby*, 530 U.S. at 372. First, "when Congress intends federal law to 'occupy the field,' state law in that area is preempted." *Id*. (When Congress chooses to occupy the field, state law can be preempted even if Congress chooses not to regulate a specific aspect of the "occupied" field. *See Chamber of Commerce of the U.S. v. Lockyer*, 364 F.3d 1154, 1169 (9th Cir. 2004).) Second, even if Congress has not occupied the field, state law is preempted to the extent of any conflict with a federal statute. *Crosby*, 530 U.S. at 372; *see English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990). Such a conflict exists either where (1) compliance with both the state and federal law is "a physical impossibility," or (2) state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Moreover, Congress' inclusion of an express preemption clause "'does *not* bar the ordinary working of conflict preemption principles'" *Sprietsma*, 537 U.S. at 65 (quoting *Geier v. American Honda Motor Co.*, 529 U.S. 861, 869 (2000) (emphasis in *Geier*)). *Boggs*, 520 U.S. at 844 (quoting *Gade*, 505 U.S. at 98).

Here, state law and regulation "which restricts the ability to carry out" the e-prescribing system would be impliedly preempted had Congress not included an express preemption

provision in the MMA. To the extent that state laws and regulations either vary dramatically with each other and the to-be-adopted federal standards, or simply do not address issues addressed by the federal standards, they "restrict the ability" to achieve what Congress sought the achieve. The existence of varying and conflicting state laws makes a uniform e-prescribing system – a key goal of the MMA – unattainable. Accordingly, state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Boggs*, 520 U.S. at 844 (quoting *Gade*, 505 U.S. at 98), and is impliedly preempted. *See also Colorado Public Util. Comm'n v. Harmon*, 951 F.2d 1571, 1582-83 (10th Cir. 1991) (where "Congress directed that safety be achieved through uniformity," state regulations that "inhibit and obstruct uniformity" are preempted).

Congress could not have intended, for example, that a multi-state vendor such as a mail order pharmacy research and analyze the laws, regulations, and practices of all the states in which it wishes to do business in order to design an acceptable e-prescribing program. The difficulties of designing a national program that complies with the various standards Congress mandated would be prohibitive if state standards are included as well. The barriers such an approach could create include complicated and various systems, enormous added expense, and contradictory regulatory requirements.

Such problems would clearly discourage physicians and pharmacists from participating in an e-prescribing program. Just as it would be difficult for a mail order pharmacy to design a program that is compliant with all state laws, physicians and pharmacists have neither the time nor training to determine whether a particular e-prescription for a patient who may fill it in another state, or which has additional state requirements because of the type of payor or for other reasons, would be legal. Requiring physicians and pharmacists to expose themselves to such professional liability risk could only serve to discourage their participation in e-prescribing programs.

Given the statutory language, the case law, and the goals Congress seeks to achieve, it is clear that, explicitly and implicitly, the federal government has fully occupied the field.

## IV. Conclusion

The MMA's e-prescription preemption provision both expressly and impliedly preempts state laws that restrict the ability to carry out the e-prescribing provisions and also state laws that pertain to the electronic transmission of medication history and certain information with respect to certain covered drugs. This broad provision supports Congress' goal of achieving national uniformity with regard to healthcare information technology. Though Congress elsewhere demonstrated the ability to limit MMA's provisions to covered part D drugs prescribed for part D eligible individuals, it chose not to do so in the preemption provision, instead preempting state laws regarding any covered part D drugs. Accordingly, MMA's e-prescription preemption provision reaches beyond just those prescriptions written for Medicare part D beneficiaries.

**APPENDIX A**
**to Memorandum**

# Summary of provisions related to electronic prescribing in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The following is a summary of the statutory provisions relevant to electronic prescribing contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

## *I. Plans may require prescriptions to be written and transmitted electronically.*

Sec 101, Part D, Subpart 1, Sec. 1860D-3(c)(1)(A) & (B), provides the means by which PDP sponsors (qualified prescription drug plans that do not offer other health or medical coverage or benefits) may mandate the use of electronic prescribing by participating providers and in-network pharmacies. The section **requires** PDPs to have in place:

- Cost-effective drug utilization management programs, including incentives to reduce costs;
- Quality assurance measures and systems to reduce measures and systems to reduce medication errors and adverse drug interactions and improve medication use; and
- Medication therapy management programs for "targeted beneficiaries" (with certain chronic diseases) that the covered part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce risk of adverse events including adverse drug interactions

While physicians are not required to participate in e-prescribing programs, PDPs may require, as a condition of participation in the plan, the use of e-prescribing technologies by participating providers and pharmacies as part of its programs and measures to meet the requirements of this provision for reducing medication errors and costs. The legislation also permits certain plans to financially reward participating physicians for doing so (see Sec 102(b)).

## *II. Prescribing health providers would receive relevant information on medical history, lower cost drugs, eligibility and benefits, drugs included on the formulary, and information on potential adverse drug interactions.*

Section 101, Part D, Subpart 1, Sec.1860D-3(e) establishes the "Electronic Prescribing Program" so that any party submitting electronic transactions under this

program for covered Part D drugs prescribed for eligible individuals must do so in accordance with the uniform standards promulgated by the Secretary as follows:

- **Application of Standards**
  - Prescriptions and "front-end" information written and transmitted electronically for Medicare beneficiaries receiving covered Medicare drugs **must conform** to the uniform standards established pursuant to this legislation no later than **April 1, 2009.**
  - The Secretary may require conformity sooner**.**
- **Delivery and Information requirements**
  - Under the Medicare electronic prescribing program, information on the following must be provided to providers and pharmacists:
    - eligibility
    - benefits (including applicable formulary and tiered formulary structure and any requirements for prior authorization)
    - information on drug interactions, warnings, and when indicated, dosage adjustments
    - other drugs listed on the medication history
    - information on the availability of generics
  - Patient *medical* history related to the drug shall be provided upon request by "professionals or pharmacists involved." However, this provision is not effective until standards have been established for such purpose and the Secretary specifies an effective date.
  - Electronic transmissions must be HIPAA compliant.
  - Information shall be exchanged in an interactive real-time basis to the extent feasible.

***III. The Secretary of HHS, in consultation with appropriate stake holders, must develop and adopt initial standards by September 1, 2005. A pilot program to test the initial standards must begin by January 1, 2006. The Secretary must evaluate the pilot program, submit a report to Congress by April 1, 2007 and issue final standards by April 2, 2008.***

Section 101, Part D, Subpart 1, Sec.1860D-3(e)(3)-(5) further provides the following:

- **Requirements:** The Secretary shall provide for the promulgation of uniform standards:

- Must be consistent with improving patient safety, quality of care, and cost efficiencies in delivery of care.

- Must be designed to avoid undue administrative burden to the extent practicable.

- Must be compatible with HIPAA administrative simplification standards (Part C), Subsection (b)(2)(b)(1) (use of standardized technology) of the Medicare bill, and general health information technology standards.

- Must permit electronic exchange of FDA drug labeling and listing information.

- Must relate messaging to the appropriate prescribing of drugs, including quality assurance measures.

- Must permit beneficiaries to designate a particular pharmacy without impact on benefits.

- **Development of Standards and Deadlines**

  - *Initial* uniform standards must be developed, adopted, recognized or modified by **September 1, 2005**.

  - The Secretary must consider recommendations (if any) from the National Committee on Vital and Health Statistics (NCVHS).

  - NCVHS must consult with:

    - practicing physicians
    - hospitals
    - pharmacies
    - PBMs
    - state boards of pharmacy and medicine
    - experts on electronic prescribing
    - other appropriate Federal agencies

- **Pilot Project to Test Initial Standards**

  - The Secretary must conduct a pilot project to test standards between **January 1, 2006 and December 31, 2006,** before uniform final standards may be promulgated.

  - Standards are exempt for this pilot project if the Secretary, in consultation with effected standard setting organizations and industry users, determines adequate industry experience exists.

- Participation of physicians and pharmacies in the pilot is voluntary; the Secretary must enter into agreements with participants who transmit prescriptions electronically under such standards.

- The Secretary must report to Congress by **April 1, 2007.**

- **Final Standards – The** Secretary must promulgate final uniform standards not later than **April 1, 2008.**

- **Federal Preemption -** Standards shall preempt any state law or regulation that:

  - conflicts with a federal standard

  - restricts the ability to carry out the Medicare electronic prescribing program

  - pertains to the electronic transmission of medication history, information on eligibility, benefits, and prescriptions for covered Medicare drugs

## *IV. Plans, hospitals and group practices are allowed to purchase hardware and software for doctors in establishing the programs*.

Section 101, Part D, Subpart 1, Sec.1860D-3(e)(6) mandates the Secretary of HHS, in consultation with the Attorney General, to establish a "Safe Harbor" exception to Stark and Fraud and Abuse statutes.

- Permits the following entities to provide hardware, software, information technology and training services to receive and transmit electronic prescription information in accordance with standards promulgated under this subsection:

  - hospitals (to medical staff)

  - group practices (to its members)

  - PDP sponsors or MA organizations (to prescribers and to in-network pharmacies)

## *V. MA-PD plans (Medicare Advantage plans that provide qualified prescription drug coverage in addition to other health and medical benefits*

- Such payments may be increased for participating physicians who significantly increase:

  - formulary compliance;

  - generic use;

- reductions in adverse drug interactions; and
- efficiencies in filing prescriptions through reduced administrative costs

### *VI. Discretionary grants are authorized to assist providers in implementing electronic prescription programs.*

Section 108 authorizes the Secretary of HHS to make grants to physicians to implement the electronic prescription drug program.

- Authorizes $50 million for fiscal year 2007, and such amounts "as necessary" for fiscal years 2008 and 2009.
- Grants may be used to purchase, lease and install software and hardware (including handheld technologies), to make upgrades to existing technologies to implement the Medicare electronic prescription program, and to provide education and training to physicians' staff.
- Requires applicant to obtain a minimum of 50% matching funds directly or from public or private entities.
- Special consideration is given to physicians serving a disproportionate number of Medicare patients and physicians serving rural or underserved areas.

### *VII. Commission on Systemic Interoperability*

Section 1012 establishes a new Commission (separate from the exiting national health information infrastructure (NHII)) to develop a comprehensive strategy for adoption and implementation of health care information technology standards.

- Prohibits the Commission from interfering with any standards development underway it the private or public sector or to replicate such activities or the HHS - NHII.
- Requires the Commission to issue a report to Congress by October 31, 2005.
- Provides membership criteria:
  - 11 members
  - Appointed by the President and House and Senate leadership
  - Nationally recognized for expertise in health finance and economics, health plans and integrated delivery systems, reimbursement, practicing physicians and pharmacists, health technology and information systems, and other related fields.

# ATTACHMENT B

## ELECTRONIC TRANSMISSION OF PRESCRIPTIONS: COMPUTER TO COMPUTER STATE COMPARISION

| STATE | ALLOW FOR ELECTRONIC TRANSMISSION OF PRESCRIPTIONS | EXAMPLES OF MISCELLANEOUS REQUIREMENTS | PRESCRIPTION AUTHENTICATION FOR NON-CONTROLLED SUBSTANCE PRESCRIPTIONS | ELECTRONIC OR DIGITAL SIGNATURES FOR NON-CONTROLLED SUBSTANCE REQUIREMENTS | LANGUAGE SIMILAR TO NABP MODEL RULES |
|---|---|---|---|---|---|
| Alabama | Yes | Electronic transmission allowed except when a specific brand must be dispensed, prescriber must write "Brand Medically Necessary" | | | |
| Alaska | Yes | | | | |
| Arizona | Yes | Verify and manually initial – must be recorded in writing by the pharmacist | | | |
| Arkansas | Yes | | | | Yes |
| California | Yes | Must be immediately reduced to writing unless and electronic copy may be printed out upon request for three years | The "furnisher" shall make a reasonable effort to determine that the person who transmits the prescription is authorized to do so and shall record the name of the authorized agent | | Yes |
| Colorado | Yes | | | | |
| Connecticut | Yes | Exclusive access or direct lines from prescriber to pharmacy not allowed; Requires same | | | |



This comparison chart is by no means all-inclusive or comprehensive. The purpose of this chart is to highlight examples of variances that exist in the electronic transmission of regulations between the states. Controlled substances are not addressed.

(This chart has been retyped in order to submit it electronically, in Word format, as an attachment to the Rx Benefit Coalition's comment letter. The original chart was submitted in testimony by the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004.)

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|---|---|---|---|---|---|
| | | verification as any oral or telephone prescription<br><br>Pharmacist must record on a form or computerized printed rx record including name and address of prescriber; name, dosage form, strength, and amount of drug prescribed; patient name and address, etc. | | | |
| Delaware | Yes | | Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order | | Yes |
| District of Columbia | Not addressed | Not addressed | Not addressed | Not addressed | Not addressed |
| Florida | Yes | Prescriptions not received in written form must be reduced to writing and retained for at least two years form date of last filling Electronically transmitted | Phamacist shall take such measures necessary to ensure the validity of all prescriptions received | | |



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|---|---|---|---|---|---|
| | | prescriptions may only be sent upon approval of patient | | | |
| Georgia | Yes | Orders must be reduced to writing and filed with the original Rx received before dispensing<br><br>Orders are consistently highly confidential and shall not be compromised by interventions, control, change, altering, or manipulation by any other person or party in any manner whatsoever | Responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of the order | | Yes |
| Hawaii | Yes<br><br>*Under jurisdiction of the Department of Health, Food, and Drug Branch* | Prescription must be reduced to writing by pharmacist immediately upon receipt and maintained in pharmacy in 5 years<br><br>If a system is used that is capable of printing a copy of the | Practitioners and pharmacist to exercise prudent and professional judgment | Prescriptions must be irrefutably traceable to prescriber by image of signature and or oral designation, electronic signature or digital signature. | |



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|---|---|---|---|---|---|
| | | prescription, the printer copy may be used to satisfy the requirement that prescriptions transmitted electronically be reduced to writing | | | |
| Idaho | Yes. The code section addressing this issue is not part of pharmacy code or rules. | | | | |
| Illinois | Yes, no specific regulation. Act allows for electronic prescriptions | | | | |
| Indiana | Not prohibited. | A prescription transmitted by practitioner by means other than writing must immediately be reduced to writing or recorded in an electronic format by the pharmacist. | | | |



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|---|---|---|---|---|---|
| Iowa | Yes | Any system or computer utilized shall have adequate safeguards designed to prevent and detect unauthorized access, modification, or manipulation of patient records and prescription drug orders. | | Computer transmission must include prescriber's electronic signature (a confidential personalized digital key, code, or number used for secure electronic data transmissions which identifies and authenticates the signatory) and is deemed the original if all other requirements are met | Yes |
| Kansas | Yes | Electronically transmitted prescription order must be immediately reduced to hard copy and be maintained for the time required by state and federal law | Order must identify the transmitter's phone number for verbal confirmation, the time and date of transmission, and identity of the pharmacy intended to receive the transmission, responsibility of pharmacist to exercise professional judgment regarding the accuracy, validity, | | Yes |



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|---|---|---|---|---|---|
| | | | and authenticity of rx order | | |
| Kentucky | Yes | | | | |
| Louisiana | Yes | Reduce to hard copy if necessary and indicate on hard copy the mode of transmission and phone number of prescriber making transmission | Verification of accuracy and authenticity is responsibility of pharmacist | | |
| Maine | Yes | | Order must be verified and authenticated by the pharmacist; must identify the transmitter's telephone number for verbal confirmation, the time and date of transmission, and the identity of the drug outlet intended to receive the transmission | If the order is transmitted by email or file transfer, it must contain the signature or electronic equivalent of a signature of the prescriber and shall be electronically encrypted ()to prevent access, alteration, or use by unauthorized person) | Yes |
| Maryland | Yes | Commercial intermediary must guarantee the confidentiality and security of transmission process | Pharmacist responsible for ensuring validity of rx order, must be conveyed in a form | | |



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|---|---|---|---|---|---|
| | | in manner approved by the board | containing an alternative method of communication for indicating that an authorized prescriber has personally originated or approved the prescription or be processed by a commercial intermediary that guarantees the confidentiality and security of the transmission process in a manner approved by the board | | |
| Massachusetts | Yes | Electronically transmitted prescriptions must have reasonable and appropriate security measures to invalidate an rx if either the electronic signature or the prescription record to which it is attached or logically associated is altered or compromised; | Electronically transmitted orders must be validated and authenticated (meaning the identities of the parties sending & receiving electronic rx data are duly verified); must utilize a system that includes a combination of technical security measures | Must have an electronic signature (defined as "an electronic sound, symbol or process attached to or logically associated with an rx record and executed or adopted by a practitioner with the intent to sign and prescription record") which is unique to an identified | |



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|---|---|---|---|---|---|
| | | Drug order shall be marked "Electronically Transmitted Prescription" | | practitioner, originated solely by and under the ultimate control of the practitioner, and capable of verification; | |
| Michigan | Yes | | Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order; technological devices shall not be used to circumvent any applicable prescription documentation and verification requirement | Prescription order to include name and address of the prescriber, an electronic signature or other board-approved mefans of ensuring prescription validity, prescriber's telephone number for verbal confirmation of the order, the date and time of transmission, and the name of the pharmacy intended to receive the transmission; | |
| Minnesota | Yes | | | | Yes |
| Mississippi | Yes | Must be filed and maintained on paper of permanent quality | Responsibility of pharmacist to exercise professional judgment | | |



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## ATTACHMENT B

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|---|---|---|---|---|---|
| | | | regarding the accuracy or authenticity of order; | | |
| Missouri | Yes | | Pharmacist shall ensure the validity of the prescription as to its source of origin | Electronic signatures is (a confidential personalized digital key, code, number or other identifier used for secure electronic data transmissions which identifies and authenticates the signatory) may be sent as part of an electronic transmissions prescription to a pharmacy or it may be applied to a hard copy to be provided to the patient | |
| Montana | Yes | | Pharmacist is responsible for assuring the validity of the electronically transmitted prescription | Both prescriber and pharmacist must have secure (encrypted or encoded) system for electronic transmission from computer to | Yes |



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|---|---|---|---|---|---|
| | | | | computer; prescriber's electronic signature or other secure method of validation shall be provided with electronically transmitted order | |
| Nebraska | Yes | | | Prescription must be a written, signed medical order and stature defines signature as a handwritten or digital signature. Cannot dispense based on electronic signature. | |
| Nevada | Yes | A practitioner may not transmit an order to the pharmacy unless he is only person who will have access to the order until it is received by pharmacy and the patient consents to the electronic transmission as well as approves | | Electronically transmitted prescriptions are not required to contain the signature of the prescriber if it contains a facsimile signature, security code or other mark that uniquely | |



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|---|---|---|---|---|---|
| | | the pharmacy to where the order will be transmitted; info must be transmitted in a way to ensure confidential info may not be altered by a person other than the pharmacist; practitioner may however use routing company in transmission; routing company may store rx info for audit purposes, but may not add to, delete or modify an rx or any confidential info it receives | | identifies the practitioner or a voice recognition system, biometric identification technique or other security system approved by the board is used to identify the practioner<br><br>Electronic prescription computer systems must be approved by BoP, and system must require user provide unique identification (fingerprint / retinal scan, PIN, or other) before each use | |
| New Hampshire | Yes | | Responsibility of pharmacist to exercise professional judgment regarding the accuracy or authenticity of order | | Yes |
| New Jersey | Yes | Must reduce to writing or enter | Prescriber must provide DEA | A practitioners electronic | |



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|---|---|---|---|---|---|
| | | into computer within 24 hours of receipt, and shall place copy in the file<br><br>Pharmacist shall not enter into any agreement with a prescribing practitioner that requires that electronic prescriptions be transmitted to a particular pharmacy or in any way denies the patient the right to have the order sent to the pharmacy of the patient's choice | number or prescriber's license number at time of transmittal; verifying authenticity of questionable orders is ultimate responsibility of pharmacist, who may request verbal verification from prescriber or agent if rx is in question | signature or other secure method of validation shall be provided with the electronic prescription unless the rx is transmitted by an authorized agent | |
| New Mexico | Yes | Order must be reduced to hard copy and be marked "Electronically Transmitted Prescription" or "ETP" | Pharmacist must exercise "professional judgment" regarding the accuracy and authenticity of the prescription | Prescriber's electronic signature, or other secure method of validation shall be provided with the electronically transmitted prescription or drug order | Yes |
| New York | Yes | Electronically transmitted prescriptions shall be | | Prescription must contain prescriber's signature (or | |



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|---|---|---|---|---|---|
| | | electronically encrypted to prevent access, alteration or use by any unauthorized person | | electronic equivalent) and be electronically encrypted | |
| North Carolina | Yes | | Pharmacist to exercise professional judgment regarding the accuracy, validity, and authenticity of order | Electronically transmitted prescriptions must contain an a "written signature" or an digital signature unique to the practitioner; order must include transmitter's phone number for verbal confirmation, time and date of transmission, and identity of the pharmacy intended to receive the transmission | Yes |
| North Dakota | Yes | | | | |
| Ohio | Yes | | Prescription not valid unless Board-approved system assures that only authorized prescribers have issued the electronically transmitted prescription | Each electronic transmission system must have "true positive identification" of the prescriber sending the | |



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|---|---|---|---|---|---|
| | | | | prescription; pharmacist must be able to verity that the rx is legitimate; compute generated signatures re not recognized as a means of positive ID | |
| Oklahoma | Yes | Prescriptions received other than in writing shall be promptly recorded in writing by the pharmacist and the written record shall constitute the original prescription | | | |
| Oregon | Yes | There shall be no additional charge to the patient because the prescription order was electronically transmitted | | | Yes |
| Pennsylvania | Yes | | | | |
| Rhode Island | Yes | | | Prescription must contain the prescriber's electronic or digital signature (defined | |



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|---|---|---|---|---|---|
| | | | | as an electronic sound, symbol or process attached to or associated with the rx) | |
| South Carolina | No | | | | |
| South Dakota | No | | | | |
| Tennessee | Yes | No person or entity may supply electronic equipment to a prescriber in exchange for transmitting orders (Safe harbor) | | Order must include phone number or authorized prescriber (to allow verbal confirmation of the validity and accuracy of order), date & time of transmission, name of pharmacy to which order is being transmitted, prescribing practitioner's electronic signature or other secure method of validation (electronic signature is process that secures the user authentication, or proof of identity at the time signature is generated – ex. | Yes |



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|---|---|---|---|---|---|
| | | | | biometrics, fingerprints, retinal scans, hand written signature verification, etc.) and identify of prescriber's agent if applicable. | |
| Texas | Yes | | Pharmacist to exercise sound professional judgment with respect to the accuracy and authenticity of rx order | | |
| Utah | Yes | No agreement may be met between a prescriber and pharmacy requiring that the order be transmitted by electronic means from the prescriber only to that pharmacy. | Order to contain the date and time transmission and name of the pharmacy intended to receive the transmission; pharmacist's responsibility to exercise professional judgment regarding the accuracy and authenticity or order | | |
| Vermont | Yes | Order to be transmitted directly to a pharmacist in a licensed pharmacy of the patient's choice with no intervening person having | R.Ph. exercise professional judgment re accuracy, validity, and authenticity of order | | |



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|---|---|---|---|---|---|
| | | access to the prescription drug order (but does not apply to the computer transition systems and persons necessary for the electronic transmission of Prescriptions); persons other than those bound by a confidentiality agreement shall not have access to pharmacy records containing confidential information or personally identifiable information concerning the pharmacy's patients | | | |
| Virginia | Yes | | | | |
| Washington | Yes | E-prescribing system must be approved by the board; new approval required every three years | | | Yes |
| West Virginia | Yes | The prescription must be transmitted directly to a pharmacist in a licensed | Order must show date and time of transmission and name of person transmitting the order | | Yes |



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|---|---|---|---|---|---|
| | | pharmacy of the patient's choice with no intervening person having access to the prescription and must be communicated in a way to ensure against unauthorized access | | | |
| Wisconsin | Yes | | | Order must include electronic signature, or other secure method of validation, sender's name and phone number for oral confirmation, time and date of transmission, pharmacy intended to receive the transmission, and is designated as "electronically transmitted prescription" or something to that effect; | Yes |
| Wyoming | Yes | | Responsibility of pharmacy to | Electronically transmitted | Yes |



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|---|---|---|---|---|---|
| | | | exercise professional judgment regarding the accuracy, validity, and authenticity of the order | prescriptions must be authenticated by a digital signature/electronic signature (depending on method of transmission) | |



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**Submitter :** **Mr. Mark Ugoretz** **Date: 04/05/2005**

**Organization :** **The ERISA Industry Committee**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-50-Attach-1.DOC

CMS-0011-P-50-Attach-2.DOC

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
3. The submitter had intended to attach more than one, but not all attachments were received.
4. The type of document provided was a password-protected file. CMS was given read-only access to the document.

We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Ms. Virginia Bartlett** **Date: 04/05/2005**

**Organization :** **IMS HEALTH**

**Category :** **Private Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

**Issues**

Background

See Attachment.

Provisions of the Proposed Regulation

See Attachment.

CMS-0011-P-51-Attach-1.DOC

CMS-0011-P-51-Attach-2.DOC

# THE ERISA INDUSTRY COMMITTEE

1400 L Street NW, Suite 350, Washington DC 20005 (202) 789-1400 fax: (202) 789-1120 www.eric.org

**Advocating the Benefit and Compensation Interests of America's Major Employers**


April 5, 2005

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Comments on Proposed Rule Regarding Medicare Program; E-Prescribing and the Prescription Drug Program

Dear Administrator McClellan:

The ERISA Industry Committee (ERIC) respectfully submits these comments in response to proposed regulation "Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule" (42 CFR Part 423) published in the *Federal Register* on February 4, 2005. ERIC, representing the interests of America's major employers, is pleased to offer our comments on the recent CMS proposed standards for electronic prescribing in the electronic prescription drug program under Title I of the Medicare Prescription Drug Improvement and Modernization Act of 2003. This regulation details electronic prescribing standards for Medicare's new Part D, the Voluntary Prescription Drug Program.

Our primary goal in these comments is to present feedback to CMS from the standpoint of America's large employers, who will be party to the electronic prescription program through retiree health plans. A majority of ERIC's members offer a retiree health plan. We support the use of electronic prescribing for its capacity to increase accuracy, effectiveness and patient safety, as well as its potential to lower the administrative burden on healthcare providers and physicians. However, we are aware that the use of electronic prescribing warrants a cautious approach and precise uniformity of computer programs, and that all actors involved must play a role in maintaining the confidentiality of patients' medical data.

We look forward to working with you and your staff to further discuss our suggestions and recommendations. If you would like to schedule a meeting or conference call to discuss these comments, please contact Edwina Rogers, ERIC's Vice President for Health Policy at 202-789-1400.

## I. Purpose of Proposed Electronic Prescribing Regulations

On February 4, 2005, CMS released a set of proposed rules and standards for the e-prescribing and prescription drug program of the Medicare Prescription Drug, Improvement and Modernization Act (MMA). This proposal would be the first set of uniform standards for the electronic prescribing program, and would ensure interoperability between all prescribing healthcare entities, prescription dispensers, and insurers encompassed under Medicare. CMS has requested public comments on this proposal in order to tailor a comprehensive and complete final set of standards.

## II. Introduction

### A. The ERISA Industry Committee

The ERISA Industry Committee is a nonprofit association committed to the advancement of employee retirement, health and other benefit plans of America's largest employers. ERIC's members provide comprehensive retirement, healthcare coverage, and other economic security benefits directly to some 25 million active and retired workers and their families. ERIC has strong interests in proposals affecting its members' ability to deliver those benefits, their cost and effectiveness, and the role of those benefits in the American economy.

### B. Statement of Interest

The proposed rule would require Prescription Drug Plan (PDP) sponsors – as well as Medicare Advantage Organizations offering prescription drug plans and other Part D sponsors – to support and comply with final standards as soon as they come into effect. Although not all prescriptions will immediately be made electronically, Part D sponsors must be able to accommodate any that are electronic. This mandate will extend to providers that prescribe or dispense Part D drugs only when certain other standards for health information technology are in place.

Many ERIC members are PDP sponsors who would be immediately affected by final standards. ERIC maintains it necessary to incorporate the perspective of our members, America's major employers, in refining the process for any standards that will amount to new mandates.

## III. Privacy and Liability

### A. Issue for Discussion

While the benefits of moving to an electronic system are numerous, the potential for lapses in privacy is equally great. Much focus and attention must be placed on securing the transactions between doctors, pharmacies, and insurers. We are concerned that any

privacy rules CMS implements will be tangled in a complicated web of state laws that could make the policy meaningless. ERIC, along with other members of the Confidentiality Coalition, sent a letter on January 18, 2005, to Dr. David J. Brailer, the National Coordinator for Health Information Technology, addressing this issue.

### B. ERIC Recommendation: Nationwide Standards

ERIC urges that the final regulations regarding electronic prescribing include rigorous safeguards to protect patient privacy and data security. We also urge that CMS preempt state laws when it comes to privacy standards, as currently there are problems with HIPAA and other state health privacy protections, involving some states that have significantly different and conflicting requirements. It would be to the benefit of all involved if CMS adopted uniform standards for privacy and data security, and could assure these standards were utilized nationwide, to accommodate multi-state employers. If PDP sponsors and insurers were required to meet multiple privacy standards, lack of standardization would cause unnecessary confusion and reduce the efficiency of moving to an electronic system. When uniform standards are adopted and adhered to, PDP sponsors should not be held liable for any data or security loss that takes place while complying with these uniform standards.

## IV. Preemption

### A. Issue for Discussion

CMS has adopted a narrow view of when federal laws preempt state laws. Preemption occurs when a state law meets the following two-part test: "[i]s contrary to the standards or restricts the ability to carry out this [regulation]" and also "[p]ertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs under this [regulation]." This interpretation limits preemption to only prescriptions written for beneficiaries enrolled in Part D when the prescription is made, rather than all Medicare recipients. It also limits preemption to only drugs covered by Part D, while Medicare recipients can have drug coverage from other sources, even other parts of the Medicare program. Further, under this view of the preemption rule, a state law would have to be in full disagreement with the federal standards to warrant preemption, instead of a wider range of state laws that interfere with the policy goals of uniform federal electronic prescribing standards.

### B. ERIC Recommendation: Broader Preemption Provision

ERIC urges CMS to adopt a broader interpretation of the preemption provision, so that the federal law will preempt any state laws that contradict the federal standards explicitly or implicitly. This view of federal preemption has precedent and would be more effective in ensuring that the uniform federal standards for electronic prescribing are adhered to and not compromised by a patchwork of contradictory state laws. This wider interpretation of the preemption provision would make the e-prescribing standards far easier to administer for care providers, dispensers, and insurance entities, especially those

who operate in multiple states. There are several types of state laws that clearly would be prohibitive to the electronic prescribing standards, including statutes requiring that prescriptions be given by doctors directly to dispensers, laws that require patient permission to release information about certain conditions, and state prescription format laws.

## V. Stark (Anti-Kickback) Laws and Regulations

### A. Issue for Discussion (BACKGROUND (A) 3)

The Stark laws severely restrict transfers of any type of assets to healthcare providers. These laws were designed to maintain the integrity of doctors and hospitals from the reach of bribery, conflicts of interest or deal-making. The Stark laws have been interpreted to prohibit reimbursement of hospitals, healthcare providers, and dispensers of drugs for expenses involving technologies such as the purchase of hardware, software, and related training. Unfortunately, even if purchases are made for the specific purpose of advancing or simply complying with emerging health information technology standards, electronic prescribing would be covered under the law.

### B. ERIC Recommendation: Creation of Stark Law Exception

ERIC applauds the efforts of CMS to amend the anti-kickback statute in order to facilitate the training of healthcare professionals and to allow hospitals to distribute hardware and software to their doctors. While the issue is not resolved in these proposed rules, we urge CMS to support the necessary legislative change needed to create a Stark law exception for electronic prescribing as quickly as possible. Encouraging wide use of electronic prescribing must continue to be a top priority in the implementation of the MMA, and would do much to promote cost-effectiveness, save time and advance patient safety.

## VI. Messaging Standards

### A. Issue for Discussion (BACKGROUND (G))

The MMA stipulates that messages may be sent through the e-prescribing system to providers for the purpose of improving patient safety, but not for advertising purposes. The limitations for messaging, however, are nebulous and without any specifications. The final standards must include detailed stipulations on messaging.

### B. ERIC Recommendation: Limit Messaging

We urge CMS to adopt standards that allow messaging only to help protect patients. Rigorous safeguards should be in place to prevent any interference with physicians' decisions, excepting only scientific advice concerning drug conflicts, etc. Messaging input should be properly prioritized as well as limited by its timing in the prescription process; drug suggestions should not be sent to physicians by any outside sources before they make an initial recommendation. ERIC supports firm limitations on messaging

between parties via electronic prescribing systems, and supports it in order to advance patient safety only.

## VII. Pilot Testing

### A. Issue for Discussion (BACKGROUND (F))

CMS has proposed to forego any pilot testing due to what it describes as "adequate industry experience" with electronic prescribing. This has the effect of speeding up adoption of final uniform standards, but also may decrease the program's initial efficiency due to lack of a limited trouble-shooting phase. While pilot testing would delay the implementation of new systems and standards, it also may help CMS to see and avoid potential problems that may arise when e-prescribing becomes more widely practiced.

### B. ERIC Recommendation: Adoption of Pilot Testing

ERIC supports the use of pilot testing as a cost-saving and safety-enhancing practice. The decision of CMS to implement standards without first running a short pilot program may result in more electronic errors, less effective prescribing safeguards, or increased system vulnerability and instability. We urge CMS to reconsider this decision. We maintain that it would be preferable to delay the program for a short time than to start the program and risk unnecessary problems that could jeopardize the program later.

## VIII. Lack of Uniform Standard for Cancellation of Refill Orders

### A. Issue for Discussion (**§ 423.160 Standards for electronic prescribing.** *(b) Standards.* (1))

While most of the important electronic transactions are listed to be uniform among program users, there is no specific listing of a transaction for the alteration of the status of a requested refill. For example, if a drug refill is requested and a doctor wishes to cancel this request, there does not appear to be a uniform transaction to accomplish this task. Other transactions also include response transactions to verify that a command was received from the prescribing entity.

### B. ERIC Recommendation: Create Additional Uniform Transactions

ERIC recommends that prescribing healthcare bodies be able to cancel a refill order just as they are able to cancel an original prescription order, that there be a response transaction to verify that the order was accepted, and that CMS design a uniform means of doing so. This could save money for all members involved in the PDP, as prescription refills (like first-time orders) are sometimes erroneous or later deemed unnecessary. However, it would also be a matter of safety, since prescriptions that are sent to dispensers sometimes need to be altered or cancelled.

## IX. Conclusion

In conclusion, ERIC appreciates the opportunity to provide suggestions to the proposed standards, and realizes that CMS must take into account the interests and commentary of multiple stakeholders. We urge you to revise the standards as suggested here, and to mold the electronic prescription process into one that is mutually beneficial to large employers, their employees, physicians and healthcare providers, and other crucial parties to the program. ERIC firmly believes that CMS can, in cooperation with those that will be sponsoring PDPs, create comprehensive uniform standards that will implement the necessary changes in privacy rules and anti-kickback legislation, and will include all the required functions and necessary safeguards to ensure a properly working system.

As requested by CMS, ERIC is submitting these comments (without any duplicates by mail or by hand) electronically to www.cms.hhs.gov/regulations/ with the text attached in the preferred Microsoft Word format.

Sincerely,

[signed]

Mark J. Ugoretz
President
The ERISA Industry Committee

Virginia L. Bartlett
Chief Privacy/Security Officer
U.S. Operations

IMS Health Incorporated
660 West Germantown Pike
Plymouth Meeting, PA 19462
Tel: 610-834-5635
Fax: 610-260-6640
Vbartlett@us.imshealth.com

April 5, 2005

Dr. Mark McClellan
Centers for Medicare and Medicaid Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan,

IMS Health, the world's premier source of prescription intelligence, applauds the Centers for Medicare and Medicaid Services (and the advisory body, the National Committee on Vital and Health Statistics) for its work to advance the standard-setting process. As IMS Chief Privacy/Security Officer, I am pleased to offer comments on the Medicare Electronic Prescribing Proposed Rule (Fed Register Vol. 70, No. 23, Friday, February 4, 2005).

A demonstrated leader in precision statistical methodologies and accurate reporting for 50 years, IMS delivers a total picture of prescription activity across channels, locations, drug types and specialties. As a trusted partner to pharmaceutical and healthcare companies worldwide, we believe that patient information is among the most sensitive of all data and must be protected. More detailed information on IMS is attached.

In response to the CMS request for comments, IMS provides recommendations on four areas we believe will facilitate electronic prescribing. These specific suggestions are:

- Establish HIPAA Privacy as a foundation "standard";
- Develop a workable approach to preemption;
- Make inclusion of the National Provider Identifier optional until there is sufficient industry experience and a system for authentication and access; and
- Do no harm to statistical integrity during the uptake period.

IMS is available to provide assistance and further information on e-prescribing, health data privacy and standards development as needed. Thank you for your consideration of these comments.

Sincerely,

Virginia Bartlett
Chief Privacy/Security Office

**Overview of Comments on the Proposed Medicare Electronic Prescribing Rule**

Passage of the Medicare Modernization Act (MMA) codified many key changes in the health care system, including an ambitious agenda for uptake of electronic prescribing within the Medicare program. Understood within the larger context of a National Health Information Network, we view electronic prescribing as a valuable tool for improving patient safety and cutting costs. IMS HEALTH (IMS) has engaged in policymaking on HIPAA, electronic prescribing and electronic health care, and work on the National Health Information Network by monitoring the National Committee on Vital and Health Statistics (NCVHS), meeting with key policymakers on Capitol Hill and within the Department of Health and Human Services, participating in relevant coalitions in Washington, and submitting official filings on related topics (including a response to the Office of the National Coordinator for Health Information Technology's Request for Information on the NHIN and interoperability).

IMS identifies the following components of an effective implementation of electronic prescribing and realized success of the agency's electronic prescribing objectives for patient safety and cost savings. For electronic prescribing to succeed, we believe electronic prescribing must:

1. Encourage prescriber adoption and meet state requirements for prescription drug dispensing;
2. Be interoperable with existing marketplace analytics to assure broadest acceptance of the standards;
3. Facilitate the tracking of drug utilization, therapy adherence and quality systems in order to improve patient safety;
4. Maintain patient confidence about safety, security, and value of the system; and
5. Further the goals of the National Health Information Network.

Our comments analyze electronic prescribing success within this framework.

**Patient Privacy: HIPAA Should Be A Foundation Standard**

Our overarching view of both electronic prescribing and electronic health care is that attention must be paid to patient privacy, interoperability and the integrity of data systems and statistics that are key to advancing the President's goal of electronic health care, improvements in patient safety, and cost savings.

While IMS Health supports the standard setting underway as a means to motivate adoption of electronic health care, we believe acceptance may be more rapidly achieved by including as a foundation standard existing patient privacy and security protections. We believe HIPAA Privacy & Security Rules should be guiding principles for the implementation of electronic prescribing.

Recognizing and preserving the HIPAA Privacy Rule is essential to the success of e-prescribing. It is also an area that meets the adequate market experience baseline for a foundation standard as called out in the e-prescribing proposed rule. While the MMA does not require that physicians gain a patient's approval to electronically prescribe, we anticipate that as electronic prescribing, and electronic health generally, achieve market uptake, patient confidence – and willingness to participate – will be key to success. By adopting a known patient privacy standard at the outset of standard-setting, CMS may improve patient confidence in an electronic health system. A recent study found that Americans are divided on whether the benefits of electronic health care (patient safety, quality of care, etc) outweigh the risk (unauthorized disclosures of health information)[1]. Reinforcing the applicability of HIPAA as a foundation standard may help allay some of these concerns.

By applying HIPAA as a foundation standard to e-prescribing, the Department will also accomplish the baseline protections it will need to generate statistics and comparative value information from the dispensing activity that occurs inside an e-prescribing network. In particular, IMS highlights the section of the HIPAA Privacy Rule that contains the industry standard for the de-identification of patient data. Companies such as IMS already de-identify data successfully as standard practice. With HIPAA as a guide, the industry can create and release research statistics and link their own data to other types of health outcomes information. IMS believes this standard for de-identified data is an appropriate solution as CMS looks to analytics on dispensing activity, drug utilization, and therapeutic effectiveness as well as insight to therapy progression in treatment of specific diseases such as Parkinson's, analysis of concomitant medications and identification of those that might be contra-indicated in combination.

Acceptance of the HIPAA baseline is essential for anyone, including patient safety advocates, the FDA and medical researchers, who monitors prescribing activities and the drug pipeline for regulatory and other public good purposes. Prescriptions written in a new e-prescribing network may be for new patients or by physicians who have switched from paper prescriptions to electronic prescriptions. In either case, visibility is necessary to ensure valid public good results. By applying the HIPAA rules for access, CMS can capture this activity and assure statistical integrity during the uptake period.

The NCVHS aptly described the importance of privacy protections to the Secretary by stating, "the main privacy issue that needs to be resolved in an e-prescribing regulation is what rights consumers should have to limit access to their prescription records." While patient identifiable data is necessary for certain basic prescribing functions (ie: filling and claims processing), de-identifying patient data provides a means of using data for key research and patient safety and quality tracking while providing patients with the highest level of protection. We refer CMS to Dr. Alan Westin's

[1] Professor Alan Westin testifying at the National Committee of Vital and Health Statistics; February, 23, 2005.

(Professor of Public Law and Government at Columbia University) recommendation to the NCVHS that among other privacy considerations, a privacy working group should "identify and test anonymization techniques to enable both advanced medical research and data-analysis services."[2] Anonymization, or de-identification, promoted in HIPAA and the Privacy Rule for research and data analytics purposes, should be a model for data security in an electronic environment – especially at a time when security breaches and identity theft are at the forefront of public debate.

In summary, IMS urges that CMS establish the HIPAA Privacy and Security Rule as a baseline foundation standard for e-prescribing. Action taken now will facilitate confidence, establish certainty, and ensure patient acceptance of a known standard. It will also establish a means for CMS to maintain statistical integrity and evolve the value of e-prescribing.

**Preemption**

*"CMS invites comments on the scope of preemption."*

It is no surprise to see a continuation of debate on state preemption given either the intensity of negotiations during HIPAA deliberations or the much-debated use of "and" linking the two criteria for exemption of state law within the MMA.[3] If CMS chooses to stay with the current interpretation of preemption, we note the importance of investing in information solutions to help negotiate differences between federal and state law. The legal efforts involved with determining where state and federal laws intersect and diverge are extremely costly and time consuming and may well serve as yet another reason physicians cite for opting not to prescribe electronically. Thus, CMS should engage in discussions with industry on how best to bridge (using reference files) or "crosswalk" between information fields required to meet state and federal law. Doing so will diminish some of the legal and technological barriers to physician uptake.

Such crosswalks currently exist and are successful due to economies of scale (that is, large quantities of prescribing information that demand crosswalks between state and federal law enable a more cost-efficient means of creating and executing the crosswalks than if there were a fewer amount of prescriptions to consider). For example, IMS builds crosswalks between the federal and state Medicaid prescription drug rebate rules for pharmaceutical manufacturers**.** Without these information solutions, our clients would have enormous complexities involved with achieving a single rebate calculation in the

[2] Dr. Westin's full testimony to the NCVHS is available at www.pandab.org and www.ncvhs.hhs.gov, see testimony from February 23, 2005. Dr. Westin expands on the recommendation: "From the start, EMR systems need to develop the identification filters and maskers that will enable researchers and data analysts to access anonymized health records sources. Surveys have shown the public to be very nervous about researcher access to their medical records, and this calls for powerful anonymizing processes to be installed, verified, and communicated to the public from the start, not retrofitted."

[3] Relevant section of the Medicare Modernization Act cited in the Proposed Rule on Electronic Prescribing: *Federal Register*, Vol. 70, No, 23: February 4, 2005. 6258.

context of state and federal laws. Our crosswalks are a cost-efficient way of achieving a single calculation. As a company that performs this service, we know that every change in regulations adds cost and confusion to meeting state and federal law. For example, under the new MMA, we will now need to account for the transition of dual eligibles from Medicaid to Medicare. That said, crosswalks that exist on a large scale (ie: broader than a single company or case) are a cost-efficient way of negotiating regulatory differences and changes.

To this end, IMS urges CMS to define crosswalks to state law and test such information solutions in pilot testing. We also encourage the Secretary to preempt state law for the purposes of pilot testing. Without doing so, pilot testing in certain states may be unable to occur or be ineffective.

**National Provider Identifier**

> *We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliances dates alternatives to the NPI, particularly in the short term and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process…NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispenser and the NCPDP HCIdea for identifying prescribers…We are looking at various options for an alternate identifier(s) , including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this as well…"*

IMS does not believe the NPI is an adequate prescriber identifier for electronic prescribing use at this point in time. We believe there are numerous unresolved short and long term problems with the identifier that need to be resolved before the industry can achieve the experience necessary for use.

In the short-term, the NPI will not be available widely in 2006, it has never been tested in industry in any capacity, and it fails to meet CMS' definition for a foundation standard for e-prescribing. Concerns that require further experience include: use of key information fields, crosswalks between the NPI and other industry identifiers, and failure to link the identifier to physical location or mandate that there be a single identifier per prescriber. Resolution of these issues is critical to the success of the NPI as an identifier and also to e-prescribing should CMS determine the NPI appropriate for use in the future.

The limited use of key information fields is inadequate. With only one location field[4] and a lack of validation during the enumeration process[5], there is very little means for users of the NPI to authenticate the NPI against other records and thus adequately protect against fraud and abuse – already a prescribing concern. While we understand that the Final Rule on the National Provider Identifier does give the Secretary of HHS the

[4] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3450
[5] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3446

authority to use the NPI for various purposes[6], we note for CMS that the decision not to validate physician-submitted information (in order to keep enumeration costs down) renders the NPI less valuable than other commonly used physician-identifiers. As another example, we would bring to CMS' attention that an NPI is not mandatory for all individual prescribers. If an individual does not require a unique NPI for billing, or is not a covered entity under HIPAA, then they need not apply for one.[7] This leaves a potentially disruptive gap for the processing of e-prescribing transactions and normal prescription claims processing, where an identifier is needed for all prescribers.

We urge CMS to thoughtfully consider the characteristics of the NPI that, while sufficient for claims processing, are not adequate for prescribing purposes. Such a consideration would look at the NPI's inability to ensure accuracy, credibility, and usability in a prescribing environment.

Therefore, it is our recommendation that in the short-term, CMS permit use of existing, currently used identifiers for electronic prescribing purposes. Other identifiers, including the SureScripts Prescriber ID (SPI), the DEA number, medical license numbers, and other proprietary identifiers are currently used widely in the industry for prescribing purposes and we recommend continued use until an identifier can be deemed sufficiently tested and workable for all industry partners. For example, after a period of use and when CMS resolves problems (such as validation and mandatory use for all individual prescribers) the NPI potentially could be an appropriate identifier.

In the event that the NPI is used in electronic prescribing, we urge CMS to ensure that the data dissemination strategy recognizes the importance of crosswalking between the NPI and legacy identifiers. Failure to do so will compromise the quality of health care data tracking, including the prescription drug monitoring that IMS does on behalf of both the government and the private sector. More importantly to CMS, if there are not accurate crosswalks available for all stakeholders in prescription claims processing, the new identifier will not be wholly adopted in that arena, and all the existing identifiers will continue to be used along with the NPI. Administration simplification therefore depends on creation and widespread availability of crosswalks. To this end, CMS should make the NPS reference files available so that data analysis may continue unhampered. This access must be permitted beyond HIPAA covered-entities. We recommend an approach that allows for file use to those who certify their compliance with relevant HIPAA regulations, including the Security Rule, in order to ensure appropriate use of the information.

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[6] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3449

[7] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3438

Based on these concerns, IMS opposes adoption of the NPI as part of the e-prescribing rules until there the aforementioned concerns are appropriately addressed. In short, IMS urges the Secretary to in the final rule to:

1. Validate the continued use of authentication crosswalks such as the SureSpripts, DEA and Medical Education (issued by state license board) number at least until 2010;
2. Assert that within the e-prescribing network identifiers must be assigned for all individual prescribers; and
3. Mandate that physical location be tied to that prescriber.

Additionally, we do not view HCIdea as an adequate interim solution to the NPI. HCIdea is not currently widely used in the industry, does not meet CMS criteria for "adequate industry experience,"[8] and does not meet the criteria outline above.

**Other Comments: Interoperability Testing Is Needed for Metrics**

IMS believes the most efficient way to achieve the dual goals of e-prescribing and the NHIN is to facilitate, not replace, industry ability to generate metrics about prescription activity. Today, data that analyzes prescribing practices is key to many public health efforts, including tracking prescribing patterns, drug safety recalls, understanding drug utilization, treatment patterns and therapy progress, resource utilization, market trends and usage. In order to continue these essential functions, and, indeed, to facilitate the patient safety and quality tracking promise of electronic prescribing, CMS must ensure continued access to data. Continued access will prevent any inconsistencies or holds on the data flow to currently useful and thriving data tracking and analysis.

Two examples in which access to and use of de-identified data facilitate key public health functions while protecting patient privacy are:

1. In the marketplace today, the FDA requires that pharmaceutical manufacturers self-monitor and report new product market introductions to ensure appropriate prescribing and use. This is most frequently accomplished through use of statistics on dispensed prescriptions. Visibility to the data dispensed within an e-prescribing network is therefore essential to manufacturers compliance and patient safety.
2. Uses of prescription drug data by indication – where the patient is de-identified – can help to identify under-treated conditions, managed care management techniques and proper use of drugs for specific age groups, (e.g. antidepressants in children)

[8] Proposed Rule on Electronic Prescribing: *Federal Register*, Vol 70, No, 23: February 4, 2005. 6261.

These examples, each representing permissible activities under HIPAA, are also necessary for a successful e-prescribing network, EMR and NHIN. Given the critical importance of this issue, IMS strongly recommends that statistical interoperability be tested in the pilot projects and that there be two goals: 1) to assure integrity; 2) to develop a comparative base about in-network dispensing for the marketplace. Specific issues such as the impact of additional and conflicting points of collection can also be included in test requirements.

**Conclusion**

IMS appreciates the opportunity to offer these comments on this important initiative and hopes CMS will:

- Protect patient privacy and research by recognizing the HIPAA Privacy and Security Rules as a foundation standard.
- Allow for continued access to and use of de-identified patient data as set forth in the Privacy Rule;
- Explore the role information solutions can play in helping stakeholders meet requirements of state and federal laws, should the narrow interpretation of preemption remain;
- Consider the characteristics of the NPI that make it an insufficient identifier for prescribing purposes and recommend continued use of multiple identifiers for prescribing use; and
- Include statistical interoperability as a component of pilot testing to ensure ongoing data integrity.

We look forward to the next phase of electronic prescribing rulemaking and engaging in forthcoming pilot projects.

## Attachment:
## Background on IMS Health

IMS HEALTH is the world's leading provider of information, research, and analysis to the pharmaceutical and health care industry with data collection activities in over 100 countries. In the United States alone, the company collects information from pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes over 375 million de-identified records each month.

IMS HEALTH's business includes tracking patterns of diseases, treatments, outcomes, prescriptions, and sales of pharmaceutical products. The company receives and analyzes de-identified data. Using this data, we are able to assist the medical, scientific, and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. The company's databases of de-identified prescription drug transactions are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, and assessment of drug utilization patterns (i.e., on- and off-label uses and regional variations in prescribing behavior).

IMS HEALTH recognizes the sensitivity of health information and has operated with long-standing comprehensive practices to protect the privacy of individuals and preserve the confidentiality of the information we collect. These practices include: requiring that transaction data be de-identified prior to being sent to IMS HEALTH; screening records before acceptance to ensure that they are de-identified; tightly controlling access to data; requiring informed patient consent before collecting any individually identifiable information; restricting use of information; routinely auditing information practices; and entering into confidentiality agreements with data sources, employees, and clients.

**Submitter :** **Ms. Alissa Fox** **Date: 04/05/2005**

**Organization :** **Blue Cross Blue Shield Association**

**Category :** **Health Care Provider/Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

April 5, 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Via Electronic Mail

Attention: CMS-0011-P

Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people ? nearly one-in-three Americans ? among them approximately one million beneficiaries in Medicare Advantage.
BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries ? and also help slow the rate of growth in spending ? by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.
First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard. CMS should allow a period of pilot testing before final adoption of standards ? as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange ? and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

OUR ATTACHMENTS CONTAIN ADDITIONAL COMMENTS

**Issues**

Background

State preemption (Page 6258)

Proposed Rule: The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

Issues: Variations in state rules and regulations are ubiquitous. As explained in a separate letter ?Comments on E-Prescribing of Drugs and Preemption of State Laws,? BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

BCBSA Recommendation: BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress? policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

OUR ATTACHMENTS CONTAIN ADDITIONAL COMMENTS

Provisions of the Proposed Regulation

Definitions (Page 6265)

Proposed Rule: CMS proposes the following definition:

Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

Issue: The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

Recommendation: BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

Electronic Prescription Drug Program means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

OUR ATTACHMENTS CONTAIN ADDITIONAL COMMENTS

**Submitter :** **Ms. Kathleen Jaegar** **Date: 04/05/2005**

**Organization :** **Generic Pharmaceutical Association**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment.

CMS-0011-P-53-Attach-1.DOC

March 5, 2005

TRANSMITTED ELECTRONICALLY

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Sir or Madam:

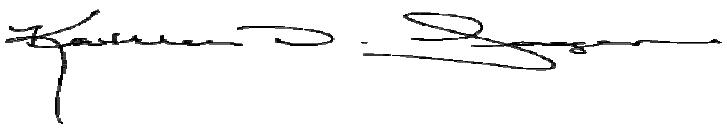
The Generic Pharmaceutical Association (GPhA) is pleased to transmit its comments on the proposed rule for electronic prescribing in accordance with Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003.

We support CMS's decision to utilize the National Council for Prescription Drug Programs SCRIPT Program standard. SCRIPT has been widely adopted and should serve as an appropriate basis for electronic prescribing in accordance with the MMA.

GPhA urges CMS to use this opportunity to promote maximum substitution of generic drugs for brand name drugs in the interests of assuring economic efficiency for taxpayers and affordability of prescription drugs to Medicare beneficiaries. The MMA clearly mandates transmission of information on the availability of lower cost alternatives for the drug prescribed to both the prescribing clinician and the dispensing pharmacist under any electronic prescription program. Such information may be of particular helpful to Medicare beneficiaries.

We commend CMS for its leadership in this electronic prescribing initiative and appreciate this opportunity to comment.

Sincerely,



Kathleen D. Jaeger
President and CEO

Generic Pharmaceutical Association (GPhA)
2300 Clarendon Boulevard, Suite 400 • Arlington, VA 22201 • ph: 703-647-2480 • f: 703-647-2481 • www.gphaonline.org

**Submitter :** **Date: 04/05/2005**

**Organization :** **WellPoint, Inc.**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see two (2) attachments

CMS-0011-P-54-Attach-1.DOC

CMS-0011-P-54-Attach-2.DOC

WELLPOINT
1 WellPoint Way
T2-1A6
Thousand Oaks, California 91362
Tel (805) 557-6761
Fax (805) 557-5827
Email: dana.mcmurtry@wellpoint.com

**Dana E. McMurtry**
Vice President
Public Policy

April 5, 2005

The Honorable Mark McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

Re: **CMS-0011-P: Medicare Program; E-Prescribing and the Prescription Drug Program**

Dear Dr. McClellan:

On behalf of WellPoint, Inc., thank you for the opportunity to comment on the E-Prescribing and the Prescription Drug Program proposed rule (proposed rule or NPRM) published February 4, 2005 in the Federal Register (CMS-0011-P). These rules represent an important component of the Medicare Modernization Act (MMA) and are critical to the continued development and implementation of electronic prescribing (e-prescribing) technology. We greatly appreciate your agency's solicitation of comments on this rule.

WellPoint, Inc. (WellPoint) is the leading health plan in the U.S. with approximately 28 million medical members. WellPoint is a Blue Cross or Blue Cross Blue Shield licensee in 13 states: California, Colorado, Connecticut, Georgia, Indiana, Kentucky, Maine, Missouri, Nevada, New Hampshire, Ohio, Virginia, excluding the immediate suburbs of Washington, D.C., and Wisconsin. One in ten Americans receives coverage for their medical care through WellPoint's health plans. We offer a broad range of medical and specialty products. WellPoint filed applications to offer Medicare Prescription Drug Plans to beneficiaries nationwide.

WellPoint understands the enormous potential of e-prescribing to improve patient safety and streamline prescription writing and filling processes. WellPoint has been a strong and early supporter of e-prescribing technology, recently implementing a $40 million pilot program to provide network physicians with hand-held e-prescribing devices. In order to realize the benefits of e-prescribing, health plans, pharmacy benefit managers

(PBMs), patients and providers need strong, uniform e-prescribing standards that have been appropriately tested and provide maximum functionality.

Our comments address a range of concerns with the proposed rule, but focus on the following principles that we believe are critical to both the successful implementation of the rule and to build a stable platform for the growth of e-prescribing:

- **Standards should be implemented within a reasonable timeframe that allows for pilot testing and adequate industry preparation.**
- **The proposed foundation standards should be pilot tested to ensure robustness and effectiveness in the new MMA environment.**
- **E-prescribing standards should be uniform nationwide, pre-empting existing state standards if necessary to achieve this goal.**
- **E-prescribing regulations must protect the ability of plan sponsors to manage the Part D benefit in a cost-effective way.**

Unless otherwise specified in the enclosed comments, WellPoint agrees with the comments submitted by our national trade associations: America's Health Insurance Plans and the Blue Cross Blue Shield Association. I respectfully refer you to their comment letters for additional recommendations regarding the proposed rule.

We look forward to continuing to work with you and your staff on the finalization and implementation of this rule. If you have any questions, please do not hesitate to contact me at (805) 557-6761 or dana.mcmurtry@wellpoint.com.

Sincerely,

Dana E. McMurtry
Vice President
Public Policy

**WellPoint Comments on Medicare E-Prescribing and Prescription Drug Program Proposed Rule**
**April 5, 2005**

## I. Background

### STATE PREEMPTION

**Issue:** The proposed rule interprets the e-prescribing section of MMA as preempting State law provisions that conflict with Federal e-prescribing program requirements adopted under Part D. HHS views its authority as mandating Federal preemption of State laws and regulations that are either contrary to the Federal standards or that restrict the ability to carry out the electronic prescription drug program requirements, and that also pertain to the electronic transmission of prescriptions or certain information regarding covered Part D drugs for Part D enrolled individuals. This limited interpretation of preemption authority is inconsistent with congressional intent and will make e-prescribing less efficient and less likely to be utilized by payors, physicians and pharmacists.

**WellPoint Recommendation:** ***State preemption should be broadly interpreted and applied to ensure a clear, predictable national scheme for all electronic prescriptions regardless of the ultimate payer*****.** With the increased attention on the value information technology (IT) can provide the health care system, policy makers are becoming more familiar with the barriers that exist to broad health IT adoption. An often noted barrier to adoption is the possibility of numerous, disjointed standards that directly impact how these systems will work in the practice setting. In fact, the Department of Health and Human Services (HHS) press release announcing the release of this proposed rule stated: "The current lack of common standards is a barrier to the use of health information technology, including e-prescribing."[1] The HHS Goals for a Strategic Framework for Health IT adoption further state that "the government has made a commitment to using common standards and architecture…The result will be a more cost-effective and efficient healthcare system."[2]

In addition, the Government Accounting Office identified in its 2004 report "HHS Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption" specific financial, technical, and cultural barriers to adopting Health IT. Technical barriers include a "lack of uniform standards for data submission and reporting." In developing health IT policy it is critical for the federal government to reduce or eliminate as many barriers to adoption as possible.

In the absence of broad federal preemption, many plans will have to meet multiple standards in the states where they operate resulting in significant costs and inefficiencies. We believe broad preemption of State law is consistent with the congressional intent of

[1] "E-prescribing proposed rule," Department of Health and Human Services-Press Release.

[2] "Goals of Strategic Framework." Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONCHIT);

MMA, as limited preemption in this area is contrary to the core purpose of establishing uniform national standards to facilitate the development of e-prescribing.

## ANTI-KICKBACK STATUTE SAFE HARBOR AND STARK EXCEPTIONS

**Issue:** Statute requires HHS to issue regulations creating a "safe harbor" under the anti-kickback statute and an "exception" under the physician self-referral statute for certain non-monetary remuneration related to e-prescribing IT items and services. These regulations are scheduled for publication in the near future. In the interim, any arrangements meeting this description must comply with an existing Stark exception or the new community-wide health IT exception (42 CFR 411.357(u)) and must not violate the anti-kickback statute.

**WellPoint Recommendation:** ***Accelerate publication of these new regulations and issue interim guidance on protected activities.*** Early experience has shown that certain types of incentive programs, including programs that provide free or reduced-cost hardware and software to prescribers, are critical to changing practice patterns and facilitating the implementation of new technology. The publication of these new e-prescribing standards necessitates clear guidance on what constitutes an allowable program. The absence of clear guidance could have a chilling effect on private sector programs to disseminate and encourage the use of e-prescribing technology. Therefore, until regulations are issued, HHS should publish interim guidance on the types of activities that will be protected.

## DETERMINATION OF "ADEQUATE INDUSTRY EXPERIENCE"

**Issue:** The regulation proposes to adopt "foundation standards," which are standards that do not need to be pilot tested because adequate industry experience with these standards is believed to exist. Adequate industry experience is based on three criteria: 1) The standard is ANSI accredited; 2) The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner; and 3) The standard is recognized by key industry stakeholders as the industry standard.

**WellPoint Recommendation:** ***The three proposed "foundation standards" should be pilot tested prior to final adoption and implementation.*** Adequate industry experience criteria must be applied in the context of how the new Part D benefit will operate under MMA. For example, there may be adequate industry experience in the current environment for the proposed ASC X12N 270/271 eligibility standard, but there is little experience with this standard among PBMs. In the new Part D environment, where direct eligibility transactions with PBMs are contemplated, adequate industry experience does not exist. The proposed "foundation standards" fail to meet the strict application of the adequate industry experience criteria and should undergo pilot testing as required by MMA. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations,

varying transaction volumes and system capabilities) and ensure we are getting the best standard with the broadest functionality. WellPoint respectfully disagrees with the recommendation of the Pharmaceutical Care Management Association, that the proposed foundation standards should be adopted absent any pilot testing.

### NATIONAL PROVIDER IDENTIFIER

**Issue:** HHS is considering, and solicits comments on, the use of the national provider identifier (NPI) before the HIPAA-required compliance date. The proposed rule also solicits comments on viable alternative provider identifiers, as the NPI will not be implemented by January 1, 2006. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007.

**WellPoint Recommendation:** ***Until the NPI compliance date is in effect, e-prescribing standards should allow the NPI as well as other identifiers to be used.*** Health insurance plans, health care providers, and PBMs are already accustomed to using a variety of identifiers such as proprietary numbers, the Medicare provider number, and the Drug Enforcement Agency (DEA) provider numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

### FORMULARY AND MEDICATION HISTORY

**Issue:** The proposed rule notes that standards are needed to permit communication of formulary information and medication history. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA-approved Standards Development Organization (SDO).

**WellPoint Recommendation:** ***Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested before adoption and implementation.*** NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history.

## II. Provisions of the Proposed Regulation

### PROPOSED REQUIREMENTS FOR PART D PLANS

**Issue:** HHS has tentatively concluded that the proposed foundation standards are not subject to pilot testing because adequate industry experience with the proposed standards already exists. Entities with electronic prescription drug programs would be required to

comply with the proposed applicable standards no later than January 1, 2006. Part D sponsors are required to have an electronic prescription drug program in place by January 1, 2006.

**WellPoint Recommendation:** ***The proposed foundation standards should undergo pilot testing. Assuming successful completion of the pilots, the compliance date for the foundation standards should be no sooner than January 1, 2007.*** As discussed above, there is not adequate industry experience with these standards in the new Part D environment to justify foregoing pilot testing. We recommend thorough pilot testing of all three proposed foundation standards and a corresponding adjustment to the implementation timeline. Assuming successful completion of the pilots, a compliance date of January 1, 2007 is reasonable and achievable.

It is also important to note that compliance with these standards will require significant resources on the part of many plans and PBMs. The accelerated timeline in the proposed rule does not provide adequate time for organizations to build these costs into their budget and operations plans for the coming year.

## PROCESS FOR UPDATING STANDARDS AND ISSUING NEWER VERSIONS

**Issue:** The proposed rule notes that "if standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards." If the updates to the standards include substantive changes, HHS will provide a formal notice and comment period. If the updates simply correct technical errors or eliminate technical inconsistencies, HHS will consider waiving notice and comment and will likely adopt the version that was previously adopted as well as the newer version. When determining whether to waive notice and comment, HHS will consider the significance of any corrections or revisions to the standard as well as whether the new version is "backward compatible" with the previously adopted version.

**WellPoint Recommendation:** ***The Centers for Medicare & Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed upon process for the annual adoption of modifications to the e-prescribing standards through an interim final rulemaking process***. This will provide maximum opportunity for stakeholder input without creating an unnecessarily lengthy process for minor modifications and updates. The SDO that initially developed an e-prescribing standard, such as NCPDP, should annually review and recommend modifications to the standard. These modifications should be submitted directly to the CMS, which should release them as an interim final rule with a 60-day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted to allow any necessary

changes to technology and business systems, as well as any necessary testing and certification between trading partners. We refer you to the discussion of potential version management processes for advancing new and retiring old versions of standards in the NCPDP comment letter (March 30, 2005; Section 1.F). The overall concepts constitute a helpful starting point for ensuring a smooth transition to new versions of standards.

## IV. Regulatory Impact Analysis

### IMPACT ON HEALTH PLANS/PBMs

**Issue:** The regulatory impact analysis finds that "plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans." The analysis also notes that the only costs incurred by health plans or PBMs would be those that are voluntarily incurred by providing "financial incentives and technical assistance to participating physicians to conduct e-prescribing." These costs are estimated at approximately $1,500 per prescriber (to implement e-prescribing hardware and software on the prescriber's behalf).

**WellPoint Recommendation:** ***While e-prescribing has the potential to make a significant contribution toward transforming the health care system, further study is needed to determine the magnitude and timing of savings that may accrue to health plans due to e-prescribing technology. Further study is also needed to determine the total cost of effective incentive programs.*** There is little doubt that e-prescribing, if properly implemented, can offer tremendous benefit to the health care system and can make an important contribution toward meaningful reform of the system. For example, e-prescribing can:[3]

- Improve patient safety with an "informed" prescription;
- Provide access to more patient information at the point of care, reducing administrative costs for presribers and pharmacists;
- Free resources to provide new, consultative, and value-added services;
- Decrease wait times and confusion due to clarification calls between pharmacy, payer, and prescriber; and
- Reduce errors due to incomplete levels of information and transcription.

[3] See, for example, Walker J et al., "The Value Of Health Care Information Exchange And Interoperability." *Health Affairs*, January 19, 2005, which found that interoperability between outpatient providers and pharmacists would reduce the number of phone calls for both clinicians and pharmacists, saving upwards of $2 billion annually. Note that this study looked at the potential impact of complete electronic health records, of which e-prescribing is a vital part. See also, Institute of Medicine (IOM). *To Err is Human: Building a Safer Health System*. National Academy Press.

These contributions may result in significant savings for the health care system, as well as improved outcomes for patients. For example:

- The Center for Information Technology Leadership (CITL) estimates savings from avoidance of adverse drug events (ADEs) greater than $2 billion nationally.
- CITL also estimates that e-prescribing could prevent 1.3 million provider visits, 190,000 hospitalizations, and 136,000 life threatening ADEs per year.

Health plans can expect to realize some of the savings generated through the implementation of e-prescribing technology, but there is little evidence to show that these savings will accrue disproportionately to health plans, or that there will be significant near-term savings. WellPoint's own research (although not generalizable) has shown that e-prescribing can significantly improve utilization of generics and reduce overall costs. By making e-prescribing an element of pay-for-performance programs, however, the value of implementation of e-prescribing for providers increases as well.

With respect to the cost estimates provided in the impact analysis, these figures may have been derived from early estimates of e-prescribing pilot programs, which involved the dissemination of hand-held e-prescribing devices to network physicians. Actual experience has shown that these early estimates were unrealistically low, as, in many cases, they did not include service costs on the hand-held devices. The early estimates also assumed that participating physicians' offices already had a base level of technology in place, which was found in practice not to necessarily be the case.

## Other Issues

### MESSAGING IN E-PRESCRIBING TRANSACTIONS

**Issue:** The proposed rule does not include any guidance on permitted or prohibited messaging, such as pop-ups, which could be part of e-prescribing transactions. While some messaging, such as reminders of generic equivalents, are consistent with the goals of the Part D program, other types of messaging are for marketing purposes and do not further the goals of the Part D program.

**WellPoint Recommendation:** ***Marketing-oriented messaging that does not lower costs or enhance safety for patients should be prohibited.*** The cost estimates for the Part D drug benefit are highly dependent on the ability of plans to manage the Part D benefit cost effectively while ensuring access to medically necessary drugs. Marketing-oriented messaging would severely undermine the ability of plan sponsors to manage the pharmacy benefit as required by MMA.

**Submitter :** **Mr. Paul Baldwin** **Date: 04/05/2005**

**Organization :** **Long Term Care Pharmacy Alliance**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-55-Attach-1.PDF

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
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We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Mr. Roy Bussewitz** **Date: 04/05/2005**

**Organization :** **National Association of Chain Drug Stores**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-56-Attach-1.DOC

NACDS' Comments on the MMA Electronic Prescribing NPRM
5 April 05

Submitted electronically: http://www.cms.hhs.gov/regulations/ecomments

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services (CMS)
Department of Health and Human Services (HHS)

File Code: CMS–0011–P

Dear Dr. McClellan:

The National Association of Chain Drug Stores (NACDS) appreciates this opportunity to comment on CMS' proposed e–prescribing "foundation" standards, which are the first set of final standards in your incremental approach to adopting final standards for an electronic prescription drug program under the MMA. NACDS' comments are organized, as CMS requested in this proposed rule, by the section of the proposed rule to which they apply, including the specific "issue identifier" that precedes that section. We have also included the *Federal Register* page numbers for convenient reference.

NACDS' chain members, Albertsons, Kerr Drug, Walgreens, and Wal–Mart, have testified on three separate occasions since July 04 at the e–prescribing standards hearings held by the National Committee on Vital and Health Statistics (NCVHS) Subcommittee on Standards and Security. NACDS and its chain members look forward to working with CMS to implement these foundation standards and to become actively involved in the MMA mandated 2006 pilots that will test candidate standards that may find their way into the Final Rule, which will be issued no later than April 1, 2008.

Founded in 1933 and based in Alexandria, Virginia, NACDS membership consists of more than 210 chain community retail pharmacy companies. Collectively, chain community retail pharmacy comprises the largest component of pharmacy practice, with 120,000 pharmacist positions and 110,000 FTE pharmacists. Chain community retail pharmacy operates over 35,000 community retail pharmacies with annual sales over $193 billion. Chain operated community retail pharmacies fill approximately 71% of the more than 3.2 billion prescriptions dispensed annually in the United States. For more information about NACDS visit www.nacds.org.

If you have any questions concerning NACDS' comments, please contact either:


Roy Bussewitz, R.Ph., J.D.
V.P., Telecommunications Standards
703–549–3001 x134
rbussewitz@nacds.org

Kevin Nicholson, R.Ph., J.D.
Director, Pharmacy Regulatory Affairs
703–549–3001 x183
knicholson@nacds.org

# NACDS' Comments

## I. Background

**A. Statutory Basis** [F.R. at page 6256]

**NACDS' Comments:** "BACKGROUND"—We agree that the HIPAA definition of "electronic media", defined at 45 CFR 160.103, should be applied to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e–prescribing standards.

"Electronic media" is defined at 45 CFR 160.103 to include both electronic storage media and transmission media, including the "internet (wide–open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media."

**A. 2. State Preemption** [F.R. at page 6258]

**NACDS' Comments:** "BACKGROUND"—The great variations in state laws and regulations, which negatively impact e–prescribing, have definitely slowed the expansion of e–prescribing. For this reason, NACDS supports an expansion of federal preemption of those state laws and regulations.

The reasons that most variations in state laws and regulations have negatively impacted e–prescribing were *not* by intent, but as a result of unintended consequences. Virtually all of these state laws and regulations were *not* intended to be barriers to e–prescribing, but many were not well enough crafted to withstand the passing of time and new technology and consequently have had that effect.

For example, some state laws and regulations use the term electronic and digital signature interchangeably. Today, many of the individuals who wrote those state laws and regulations would likely recognize the huge differences in the meaning of those terms and their very different impact on e–prescribing.

Realizing that a state educational effort was necessary to correct either the language of the laws and regulations or their interpretation, many entities, including chain pharmacies, initiated independent efforts to educate the states. This educational process was not only directed at trying to eliminate the negative impact of those laws and regulations, but also to offer specific suggestions on how to change those laws and regulations to retain the intent while eliminating the negative impact on e–prescribing.

Needless to say, this state educational process was a very slow process because of the number of states and the wide variations in the wording of their respective laws and regulations. It must be realized that this educational process will need to be continued as long as new state laws and regulations that *could* possibly negatively impact e–prescribing are enacted or promulgated and/or new technology is developed, which would require revisiting the *possible* negative impact of current state laws and regulations.

However, after all of this is said about the negative impact of the variations of state laws and regulations on e–prescribing, it is essential to emphasize that e–prescribing has increased dramatically in that environment. It is very likely though, that e–prescribing would have increased even more dramatically if there was a "total" federal preemption of the state laws and regulations that had *any* adverse impact on e–prescribing.

NACDS believes that it is important to realize that there is an *assumption* by some that designing a federal preemption law, which would *only* preempt those state laws that adversely impact e–prescribing, would be an easy task. However, this task would require an educational effort directed at the federal government, which may be no easier or less time consuming than the state educational efforts.

In addition, the federal educational effort will also have to continue just as long as the state educational efforts… as long as new federal laws are enacted or promulgated that *could* possibly negatively impact e–prescribing and/or new technology is developed, which would require revisiting the *possible* negative impact of current federal laws.

NACDS suggests that CMS request NCVHS to hold a reasonable number of days of hearings… perhaps 5–10 days of hearings… concerning whether or not federal preemption should be expanded and if so, how best to expand that preemption. However, *before* CMS/NCVHS even announces its intent to hold such hearings, they must very carefully frame the issues(s) of that *possible* expanded federal preemption so that elected officials and their constituents are not unduly alarmed.

In addition, CMS/NCVHS must acknowledge that virtually all of the state laws and regulations negatively impacting e–prescribing were certainly well intentioned, but in many cases not crafted precisely enough to withstand the passage of time and the development of new technology, which lead to unintended negative impacts on e–prescribing.

One of the reasons some of the state laws and regulations are now perceived as not written well, is that the authors were writing these laws in the very early days of e–prescribing when no one could predict the future directions of e–prescribing. Many states did as good of a job drafting their laws as they could be reasonably expected to do at that time.

In addition, CMS/NCVHS must make it clear that any *possible* expansion of federal preemption is *not* aimed at politically sensitive issues (e.g., sharing HIV or mental health information). The narrow focus of any possible expansion of federal preemption must be e–prescribing between prescribers and dispensers.

Now, to answer the specific questions posed by this NPRM section. While NACDS agrees with the proposed rule to preempt state law and regulation provisions that conflict with federal electronic prescription program drug requirements that are adopted under Part D, we urge CMS to request that NCVHS hold hearings that would determine whether or not federal preemption should be expanded and if so, to determine specifically how that would be done.

NACDS agrees that the "Relation to State Laws" section of the Act mandates federal preemption of state laws and regulations that are either contrary to the federal e–prescribing standards, or that restricts the ability to carry out or stand as an obstacle to the Medicare Part D electronic prescription drug program requirements. Again, NACDS urges CMS to request that NCVHS

hold hearing that would determine whether or not that federal preemption should be expanded, and if so how.

NACDS also believes that this preemption provision, addressed in the paragraph immediately above, applies only to electronic prescription transactions.

NACDS believes that NCVHS federal preemption expansion hearings could be beneficial even if CMS does *not* now currently have the Congressional authority to expand federal preemption. Those same hearings could provide the essential information necessary for Congress to revisit the issue of expanding federal preemption of state laws and regulations that negatively impact e–prescribing. It will certainly be necessary for Congress to act to increase federal preemption to e–prescribing that exists beyond the MMA Part D program. The continued growth of e–prescribing is dependent upon the creation of *one* national set of e–prescribing standards for *all* e–prescribing.

**D. Current Prescribing Environment** [F.R. at page 6260]

**NACDS' Comments:** "BACKGROUND"—The *Current Prescribing Environment* should also reflect that community pharmacies have significant patient clinical medication information. This awareness is essential to local, regional, and national health information networks so that they understand the value of including community pharmacies in their electronic information sharing networks.

Specifically, Congress recognized that community pharmacies have a vital role in reducing medication errors and adverse drug interactions as well as improving medication use when it enacted the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) Public Law 101–508. OBRA '90 applies only to Medicaid recipients, but it was not long before all the states passed laws that assured that this higher standard of pharmacy care for Medicaid patients would be available for all of their citizens.

OBRA '90, and the state laws that expanded OBRA '90's coverage to all state citizens, requires a set of prospective Drug Use Review (DUR) requirements that are more expansive than those required by the MMA. In addition, and more to the point of this comment, OBRA '90 also required that:

> "A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:
> "(aa) Name, address, telephone number, date of birth (or age) and gender.
> "(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
> "(cc) Pharmacist comments relevant to the individual's drug therapy."

The OBRA '90 required maintenance of information concerning patients' diseases, allergies, drug reactions, list of medications and relevant devices, certainly has value to be included within patients' electronic health records (EHRs) in addition to other e–prescribing information required by the MMA.

**F. Evolution and Implementation of an Electronic Prescription Drug Program** [F.R. at page 6261]

**NACDS' Comments:** "BACKGROUND"—We agree with CMS' proposed criteria to assess "adequate industry experience" as the rational for supporting CMS' proposed foundation standards without the need to be first pilot tested:

1. The standard is American National Standards Institute (ANSI) accredited;
2. The standard has been implemented by entities to which the final standard will be applied in multiple e–prescribing programs with more than one external health care partner; and
3. The standard is recognized by key industry stakeholders as the industry standard.

NACDS believes that the first of these CMS proposed criterion to assess "adequate industry experience" is an essential safeguard of broad industry input into the development of the candidate standard. The ANSI accreditation process of the standard runs largely parallel to the ANSI accredited standards development organizations (SDO) development of that standard. There is only about a 6–8 week lag in ANSI accreditation of the standard as an *American National Standard* to the SDO's adoption of that standard. Thus, while the ANSI accreditation process of the standard provides an independent verification of broad industry input into the development of that standard, it does not unduly slow the adoption and implementation of that standard.

In addition to these three CMS proposed criterion to assess "adequate industry experience", NACDS strongly suggests that the standard must also be developed and adopted by an ANSI accredited SDO such as NCPDP, HL7, and X12.

**NACDS' Comments:** "BACKGROUND"—CMS must adopt/acknowledge a standard development organization's (SDO) standards version control/management process that would be used to evolve currently adopted standards and to determine an appropriate implementation time sequence, consistent with the Administrative Procedures Act and other applicable legal requirements.

NACDS continues to believe that the ANSI accredited SDOs play the critical role of bringing together industry stakeholders and providing the forum to develop industry consensus standards, including standards for version control/management. NCVHS' role should continue to be one of holding hearings to assuring greater public input and debate on the SDO adopted standards and then to recommend those standards, supported by the information derived from its hearings, to the Secretary of HHS.

Specifically, CMS must adopt/acknowledge a SDO's process to support a range of standards that are backwards compatible. Backwards compatibility allows for "interoperability" over a range of standard versions. The range must be advanced as industry use dictates, which is best determined by the respective SDO. The result is a "moving range" of standard versions.

The SDO version control/management process, which NACDS described in the paragraph immediately above, would advance the industry as a whole, but does not force everyone to stay in lock–step in order to maintain interoperability. Naming only one version of a standard as the only acceptable version would impede progress and innovation. On the other hand, requiring the simultaneous adoption of a newer version could create disruptive and inefficient transitions. The solution is for SDOs to approve a moving range of standards, which would allow the use of a newer version while still supporting older versions.

Market forces, which are more perceptible to the SDO, will dictate the moving range of standard versions. Competition supports the moving range of standard versions, which allows entities to leapfrog from an older to a newer version when they perceive the time is right to maximize efficiencies. For leapfrogging to occur there must be a minimum of two newer versions. A moving range of standard versions also supports flexibility of decision making in a competitive market.

The many positives of CMS adopting or acknowledging the above described SDO version controlled/managed process for MMA standards, strongly suggests that CMS consider that same process for the HIPAA named standards. It is NACDS' understanding that the community pharmacy SDO, NCPDP, is willing to sit down with CMS and work out the particulars of developing and coordinating such an SDO controlled/managed version process for both the MMA and HIPAA named standards.

**G. Electronic Prescription Drug Program** [F.R. at page 6261]

**NACDS' Comments:** "BACKGROUND"—We agree with NCVHS and CMS that it is very important to adopt national unique pharmacy and prescriber *identifiers* for e–prescribing program transactions *as well as the HIPAA transactions*. NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D

However, CMS must understand that e–prescribing not only requires a unique provider identifier, but also requires a unique routing number that can be used to route an e–prescription to one of a prescribers' multiple practice sites. The NPI, being a *unique* identifier, can only be used to route to one practice site.

It would be much more efficient, and far less costly, to be able to use the unique provider identifier as also the number for routing to one of a prescribers' multiple practice sites. To this end, NACDS strongly suggests that CMS ask NCVHS to hold hearings to determine whether or not the NPI 's functionality could be increased to include routing to multiple prescriber sites.

If these hearings determine that such multiple routing functionality is *not* possible, CMS must do everything it can to make it as easy and as cost effective as possible to facilitate that multiple routing, including allowing the continued use of the different methods being used today.

Again, NACDS strongly recommends that HHS require the use of the NPI as the *provider identifier* for electronic prescription program transactions under Medicare Part D, and for that matter, also for all the HIPAA transactions.

Congress thought that these unique identifiers were critical when it enacted HIPAA in 1996 and at that time required the Secretary of HHS to adopt them. The NPI Final Rule states that the effective date that providers may apply for a NPI is 23 May 05 and that the compliance date for the NPI is "no later than" 23 May 07.

The implementation date for the Medicare Part D drug benefit (i.e., 1 January 06) falls between the date that providers may become enumerated with the NPI and the "no later than" compliance deadline. Therefore, NACDS strongly recommends that CMS immediately begin enumerating all

prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans. This NACDS recommendation is consistent with NCVHS' urging that HHS accelerate the enumeration of all providers to support transition to the NPI for e–prescribing. CMS should require the use of the NPI in the Medicare Part D drug benefit e–prescribing programs beginning 1 January 06.

NACDS strongly recommends that CMS *not* consider an alternative unique identifier to the NPI, including in the short term, because such implementation would create additional and unnecessary expenses for our chain pharmacy members with *no* benefit. Specifically, the "short term" would have to represent the time frame of the less than two months that remain before the NPI effective date of 23 May 05 when prescribers may begin requesting NPI enumeration by CMS. We strongly recommend that CMS focus its NPI enumeration on Medicare Part D prescribers.

**NACDS' Comments:** "BACKGROUND"—CMS' question, with an invitation for the public to comment, concerns the possible use of the HCIdea number as an alternative for identifying prescribers, which was based on the NPI *not* being available. As NACDS recommended in our comment immediately above, CMS should "immediately begin enumerating all prescribers who could submit e–prescriptions for covered Medicare Part D drugs prescribed for Medicare Part D eligible individuals who are enrolled in Part D plans." If CMS begins performing this enumeration now, the NPIs should be available in plenty of time before the January 06 implementation of the Medicare Part D drug benefit.

NACDS does *not* recommend the use, short term or otherwise, of NCPDP's HCIdea number to be used for identifying prescribers because such a charge would incur additional costs for a very short term use of less than 2 months before providers may apply for NPI enumeration.

NACDS also recommends that CMS, after it adopts the NPI as the Medicare Part D e–prescribing programs' unique prescriber identifier, work with the State Medicaid Agencies to assure that they are *not* using federal dollars to support any other unique identifiers.

If the NPI is *not* available by 1 January 06, NACDS strongly recommends that community pharmacies be allowed to continue to use the pharmacy and prescriber numbers that they are using today. This recommendation would not only allow the time for CMS to do the necessary enumeration of providers, but it would *not* increase costs to community pharmacies. No other interim solution of an alternate unique provider identifier is necessary.

**NACDS' Comments:** "BACKGROUND"—NACDS recommends that the *new* formulary and medication history candidate standard which *may* be affirmatively voted upon by NCPDP's membership and approved by their Board of Trustees by sometime in July *at the earliest*, should *not* be considered by CMS as a *foundation* standard because there will *not* be sufficient time from July 05 to January 06 to meet one of CMS' proposed criteria… to demonstrate *adequate* industry experience, which is necessary to avoid being required to be included in the MMA 2006 pilots. The "*adequate* industry experience" must refer to the industry experience with the standard as approved by the SDO, *not* the RxHub protocol proprietary *candidate* standard that went through SDO modifications before being adopted as an SDO standard. The industry experience with the proprietary *candidate* standard must be viewed as irrelevant.

**NACDS' Comments:** "BACKGROUND"—We agree with CMS' proposed "critical characteristics for formulary and benefit data standards" set out in the 3rd column of F.R. page 6263. However, it is imperative that these proposed "critical characteristics" be combined with

CMS' three proposed criteria" to assess adequate industry experience, which are set out in the 1st column of F.R. page 6261.

Please see our comments on those proposed criteria at "Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program". Please see NACDS's 3rd comment under *"Background"— "G. Electronic Prescription Drug Program"*, which explains why NACDS recommends that the *new* formulary and medication history standard that *may* become a NCPDP standard later this year, should *not* be considered by CMS as a *foundation* standard.

**H. Summary of Status of Standards for an Electronic Prescription Drug Program** [F.R. at page 6264]

**NACDS' Comments:** "BACKGROUND"— We agree with the foundation standards and their specified application as proposed by CMS:

- NCPDP SCRIPT Standard Version 5;
- X12 270/271; and
- NCPDP Version 5.1.

For the reasons mentioned at NACDS' 3rd and 4th comments above at "Background"—"G. Electronic Prescription Drug Program", we do not believe that the adequate industry experience conditions have been met to include *any* formulary and medication history candidate standards as a foundation standard.

NACDS further agrees with CMS' proposed strategy to phase–in implementation of the MMA e–prescribing standards by requiring providers, dispensers, MA–organizations, and PDPs engaged in e–prescribing to comply with the proposed foundation standards, as set out in this NPRM, by no later than 1 January 2006 and at future dates as compliance with other e–prescribing standards are adopted in subsequent rulemaking. We also agree that pilot testing will be required for "candidate" standards *unless* they meet the exception for adequate industry experience criteria as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*.

**NACDS' Comments:** "BACKGROUND"— We agree with the three foundation standards that are proposed by CMS… please see our comments above at *"Background"—"H. Summary of Status of Standards for an Electronic Prescription Drug Program"*. NACDS also agrees that it is essential that foundation standards be ANSI–accredited *and* meet the adequate industry experience criteria, as proposed by CMS at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, which will facilitate interoperability with later industry–adopted standards for EHRs as well as interoperability across software and hardware products.

## II. Provisions of the Proposed Regulation [F.R. at page 6264]

**NACDS' Comments:** "PROVISIONS"—NACDS is not aware of any reasons why Part D plans should be required to use the MMA standards for e–prescribing transactions within the enterprise. We are not aware of any potential negative implications or any disadvantages that might occur if these Part D plans in–house e–prescribing transactions were excluded from CMS requirements to comply.

E. **Proposed Standards** [F.R. at page 6265]

**NACDS' Comments:** "PROVISIONS"—We agree with CMS' decision to propose the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as foundation standards because there is adequate industry experience to forego pilot testing. NACDS also agrees with CMS' decision that the Prescription Fill Status Notification Transaction of SCRIPT lacks the necessary industry experience and thus may not be included as a foundation standard in this proposed rule, but will instead be required to go through the MMA 2006 pilot testing.

**NACDS' Comments:** "PROVISIONS"—In addition to the comments that NACDS has already made about e–prescribing transaction standard version change, the 2nd NACDS comment at *"Background"—F. Evolution and Implementation of an Electronic Prescription Program"*, we also recommend that CMS should coordinate the version updating process for the e–prescribing transaction standard with the maintenance and modifications of the applicable HIPAA transaction standard. This updating process could certainly be done by CMS by simply referencing the relevant HIPAA standard so that the e–prescribing transaction standard could be updated automatically in concert with any HIPAA standard modification. Keeping MMA e–prescribing transaction standard versions in sync with HIPAA transaction standards is critical.

## III. Collection of Information Requirements [F.R. at page 6267]

**NACDS' Comments:** We do not find it necessary to comment on any of the information collection requirements (i.e., the *Paperwork Reduction Act* requirements).

## IV. Regulatory Impact Analysis [F.R. at page 6268]

### A. Overall Impact [F.R. at page 6228]

**NACDS' Comments:** "IMPACT ANALYSIS"—The proposed MMA e–prescribing transaction standards *must* be available for the January 2006 implementation of the Medicare Prescription Drug Program for use by the PDPs that are required to support e–prescribing. This PDP e–prescribing requirement can be expected to *greatly* accelerate prescribers' use of e–prescribing. In addition, an increased number of prescribers outside of the Medicare program can be expected to begin using e–prescribing based on the positive experiences of their Medicare colleagues.

**NACDS' Comment:** *"IMPACT ANALYSIS***"—***In addition to the comments NACDS made above at "Background "— "D. Current Prescribing Environment*", about the federal law and state laws that already require community pharmacies to provide patient safety prospective drug utilization review (pro–DUR) before the medication is dispensed, we would also like to acknowledge that the e–prescribing standards that deliver relevant patient and medication information to the prescriber at the time of prescribing, *in a non–commercial message format*, will add another level of safety checks**.**

NACDS is very concerned that MMA e–prescribing could quickly be converted into another marketing media venture by commercial interests. When Congress enacted the MMA it gave the Secretary of HHS very clear instructions that electronic prescribing standards shall be adopted

that "allow for the messaging of information only if it relates to the appropriate prescribing of drugs…"

We recommend that CMS includes in its e–prescribing Final Rule, as a general e–prescribing format standard, that MMA e–prescribing must *not* include inappropriate messaging of information. Such inappropriate messaging certainly includes financial incentives that attempt to influence the prescriber's selection decision of medication or of dispenser. If commercial messaging is not strictly prohibited by CMS, as a general format standard, such messaging could have the undesired effect of slowing the implementation of e–prescribing by prescribers and dispensers.

Physicians should see the full range of pharmacy choices that the beneficiary has to obtain their covered Part D drugs, including obtaining extended supplies of medications at retail pharmacies as required by law. The information should include the different cost sharing requirements, but the presentation of the information should not be such that it directs or steers beneficiaries to a particular pharmacy.

Physicians should also not be provided incentives to steer beneficiaries to a particular pharmacy. The information should also include a notation that the beneficiary has the choice of obtaining an extended supply of covered Part D drugs at their local retail pharmacy, and is not required to use a mail order pharmacy.

NACDS also agrees with CMS that the Medicare Part D prescription drug benefits medication therapy management (MTM) programs will improve medication use and further reduce the risk of adverse events, including adverse drug interactions. NACDS believes that electronic prescribing will make available important information to the community pharmacy provider that will help them provide medication management services in the retail pharmacy, such as medication history, and eventually medical history.

The success of these MTM programs, however, will be dictated primarily by whether Part D plans provide these important MTM services through retail pharmacies–which is the preferred way of providing these services to achieve optimal health care outcomes–or whether plans will simply require beneficiaries to obtain these services through telephone services.

**B. <u>Impact on Health Plans/PBMs</u>** [F.R. at page 6269]

**NACDS' Comments:** "<u>IMPACT ANALYSIS</u>"—We cannot comment on this section because we do not have any information on the possible impact of e–prescribing on Health Plans/PBMs.

**C. <u>Impact on Prescribers</u>** [F.R. at page 6270]

**NACDS' Comments:** "<u>IMPACT ANALYSIS</u>"—Although the MMA e–prescribing programs consist of both prescribers and dispensers, all of CMS' attention to provide incentives to encourage e–prescribing has been focused only on one–side of this equation… the prescribers.

NACDS certainly supports providing incentives for prescribers, but believes that incentives for dispensers, including community pharmacies, should be provided as well. Not to provide incentives to dispensers could be viewed as financially penalizing them for doing the right thing

early by spending the necessary money to be prepared for e–prescribing when the prescribers are ready. In addition, community pharmacies pick up the entire e–prescribing transaction charge… prescribers don't pay any transaction charge. This positive early action by dispensers should be acknowledged by also providing them with incentives to quickly implement e–prescribing.

**D. Impact on Pharmacies and Other Dispensers** [F.R. at page 6271]

**NACDS' Comments:** "IMPACT ANALYSIS"—Please refer to our comment immediately above at *"Impact Analysis"—C. Impact on Prescribers"*. In addition, we certainly agree with the e–prescribing benefits described in the testimony of four of our chain members before NCVHS on three separate occasions beginning in July 2004.

We are delighted to see that CMS used the information in the preamble to the e–prescribing NPRM that NACDS provided: "indicating that 75 percent of the 57,208 pharmacies in the U.S. already have e–prescribing capability."

It must be noted that the motivation for these pharmacies to become e–prescribing capable is *not only* the reduction in administrative costs (i.e., reduced time–consuming phone calls to physicians and improved prescription communication between prescriber and dispenser, for example, reduction in illegible handwritten paper prescriptions), but also the awareness that e–prescribing will improve patient safety.

Pharmacists, like other health care providers, are very concerned about patients' quality of care and are very eager to do what they can to improve it. E–prescribing is as much about increasing the opportunity for pharmacists to work more closely with the patient's prescriber and play an expanded role in patients' care. E–prescribing will present new opportunities to make pharmacists' professional roles more challenging and meaningful. CMS should be aware that these professional benefits to pharmacists are perhaps as much of a driving force to become e–prescribing capable as is the reduction in administrative costs.

**F. Impact on Others** [F.R. at page 6271]

**NACDS' Comments:** "IMPACT ANALYSIS"—We can not comment because we do *not* have any first hand information on the impact of e–prescribing on the "others" that CMS listed (i.e., technology vendors, pharmaceutical and medical device manufacturers, public health organizations, research and academic institutions, and professional lay organizations).

**G. Impact on Small Businesses** [F.R. at page 6271]

**NACDS' Comments:** "IMPACT ANALYSIS"—Some or NACDS' chain members may fit the definition of "small businesses" and therefore NACDS is especially sensitive to and agrees with CMS' statement that, " there will be a distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale." However, our comments above at *"Impact Analysis"—"D. Impact on Pharmacies and other Dispensers"* certainly apply to these small business members as well as all of our other chain pharmacy members.

**H. Effects on States and Federalism Statement** [F.R. at page 6272]

**NACDS' Comments:** "IMPACT ANALYSIS"—We agree with CMS that the annual expenditures for installing the capability of e–prescribing will *not* reach the *Unfunded Mandate Reform Act's* threshold of $110 million annually. NACDS addressed its concerns about federal preemption above at *"Background"—"A.2. State Preemption"*. We also agree with CMS, that its discussion in the *"State Preemption"* section and in this section constitute the Federalism summary impact statement required by Executive Order 13132.

**I. Conclusion and Alternatives Considered** [F.R. at page 6272]

**NACDS' Comments:** "IMPACT ANALYSIS"—Our comments above, at *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, state that NACDS supports CMS' proposed foundation standards because, in part, that they were developed by an ANSI accredited SDO and that they have had adequate industry experience. Therefore, NACDS does *not* believe that the alternative of pilot testing the foundation standards is necessary or desirable. Pilot testing would be redundant at best. The "broad" industry experience provides much better evidence that these standards are accepted by the industry than would pilot testing, which would be of a much smaller scale.

However, NACDS is very sensitive that the word "adequate" in "adequate industry experience" must *not* be minimized. This concern is at least part of the reason behind our 3rd comment above at, *"Background"—"F. Evolution and Implementation of an Electronic Prescription Drug Program"*, suggesting that the proposed formulary and medical history candidate standard must be included in the 2006 MMA required pilot tests.

NACDS would certainly *not* support CMS' adoption of MMA e–prescribing standards that were merely proprietary standards (i.e., not developed by an ANSI accredited SDO) even though they have adequate industry experience. Development by an ANSI accredited SDO and adequate industry experience must be evidenced before CMS should even consider that candidate standard as a MMA e–prescribing standard.

**Submitter :** **Mrs. Lorraine Doo** **Date: 04/05/2005**

**Organization :** **CMS**

**Category :** **Individual**

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

**Issues**

Background

This is the background

Provisions of the Proposed Regulation

yes

Regulatory Impact Analysis

yes

Collection of Information Requirements

yes

CMS-0011-P-57-Attach-1.DOC

# CAHIT E-PRESCRIBING IMPLEMENTATION WORK PLAN

| Project/Task Description | Lead Agency | Partners | Start Date | Milestones/Deliverables | End Date |
|---|---|---|---|---|---|
| **MEDICATION and PRESCRIBING INFORMATION STANDARDS** | | | | | |
| Physician Labeling Rule | FDA | HHS | | • Final rule (8/04) | • |
| Electronic Drug Listing Rule | FDA | HHS | | • NPRM – 11/04<br>• Final rule –11/05 | • |
| Guidance document on electronic labeling | FDA | HHS | | • Draft published 2/04<br>• Standards on HL7 ballot 5/04<br>• Final guidance 6/04 | • |
| ELIPS (Electronic Labeling Information Processing System) | FDA | AHRQ/ASPE | | • Initiate software development 2004<br>• Approved Rx products started 12/04<br>• Approved Rx products completed 12/05<br>• Extend to other drug products 12/06 | • |
| ELIST (Electronic product listing) | FDA | | | • Initiate software development 12/04<br>• Implement system – 12/06<br>• Inventory completed – 7/08 | • |
| Substance Registration System (to generate unique ingredient identifiers –UNII) | FDA | AHRQ, ASPE, NLM | Ongoing | • UNII publicly available via NLM 12/04 | • |

| Project/Task Description | Lead Agency | Partners | Start Date | Milestones/Deliverables | End Date |
|---|---|---|---|---|---|
| Structured product label (enable drug to drug interactions, drug to allergy checking, drug to laboratory results checking, dosage checking against patient's weight) | FDA | VA and NLM | | • HL7 standards 5/04<br>• SPL extended to meet requirements of highlights section of prof. Labeling rule—Start 03/04<br>• HL7 committee level ballot by 1/05<br>• SPL with highlights standard 10/06 | • |
| Rx Norm | NLM | | | Federal adoption pending, first release in April 04, updated version available? | |
| Other Medication terminology (VA reference terminology) | FDA/ VA | | | FDA to use in labeling starting 12/05 (Depends on Prof. Labeling Rule) | |
| Knowledge/evidence representation standards | AHRQ | NCVHS, FDA, CMS, ASPE, outside consultants | 03/01/04 | Scope defined<br>Initial inventory created | 09/01/04<br>6/01/05 |
| NCPDP messaging standard for prescribing information | CMS | NCVHS | 03/01/04 | Recommendations | 11/01/04 |
| Electronic Signature standards | CMS | DEA | 05/01/04 | | 06/01/05 |
| **ELIGIBILITY AND BENEFITS INFORMATION STANDARDS** | | | | | |
| | CMS | | 03/01/04 | | |
| NCVHS hearings and private sector initiatives | NCVHS | E-Health Initiative | 03/01/04 | | 09/01/05 |

| Project/Task Description | Lead Agency | Partners | Start Date | Milestones/Deliverables | End Date |
|---|---|---|---|---|---|
| **MEDICAL HISTORY INFORMATION** | CMS | OGC, OCR | 03/01/04 | | |
| Analysis of what information can be exchanged under current law (state and federal) | NCVHS | OCG, OCR, CMS, ASPE | 03/01/04 | | 09/01/05 |
| HL7 data interchange standards project | ASPE | | | | |
| Generate and prioritize e-prescribing requirements and communicate to HL7 SIG | CAHIT | | | | |
| **REGULATORY STRATEGY FOR PROMULGATION OF E-PRESCRIBING STANDARDS** | | | | | |
| | CAHIT | MMA (Medicare Council) | 03/01/04 | Final standards promulgated | 04/01/08 |
| Develop timeline for rule making process based on OGC interpretation of statute | CMS | OGC | 05/01/04 | | 07/0104 |
| **DEMONSTRATION PROJECT TO TEST INITIAL STANDARDS** | | | | | |
| | CMS | FDA/NLM/AHRQ<br>MMA | 06/01/05 | Launch 1/2006 and report to Congress on 4/2007 | 04/07 |
| Recommend adoption of initial standards for e-prescribing | NCVHS | CAHIT | 03/01/04 | Interim report to Secretary<br>Final recommendations | FALL 2004<br><br>08/01/05 |
| Plan scope and stakeholders to participate in demonstration project | CMS | CAHIT/MMA | 09/01/04 | 2004-2005 | |
| Plan evaluation component of demonstration project | CMS | AHRQ | 09/01/05 | 2004-2005 | |
| Launch demonstration project | CMS | | 01/01/06 | 1/01/06 | 1/01/06 |

DRAFT

**Submitter :** **Ms. Theresa Doyle** **Date: 04/05/2005**

**Organization :** **Healthcare Leadership Council**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-58-Attach-1.DOC

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**CENTERS FOR MEDICARE AND MEDICAID SERIVICES**
**OFFICE OF STRATEGIC OPERATIONS & REGULATORY AFFAIRS**

Please note: The attachment cited in this document is not included for one of the following reasons:

1. Improper format.
2. The submitter did not follow through when attaching the document.
3. The submitter had intended to attach more than one, but not all attachments were received.
4. The type of document provided was a password-protected file. CMS was given read-only access to the document.

We cannot provide this electronic attachment to you at this time, but you would like to view any of those that are not posted on this web site, you may call CMS and schedule an appointment at **1-800-743-3951**. Those comments along with its attachment(s), that could not be posted, will be available for your viewing at that time.

**Submitter :** **Ms. Karen Eckert** **Date: 04/05/2005**

**Organization :** **Wolters Kluwer Health/Medi-Span**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Comments relating to background and regulatory impact analysis are included in the attachment.

CMS-0011-P-59-Attach-1.DOC

Centers for Medicare and Medicaid Service
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

***Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423) – Comments***

Dear Centers for Medicare and Medicaid Services:

Wolters Kluwer Health is pleased to submit the following comments regarding the Medicare Prescription Drug Benefit NPRM.

Wolters Kluwer Health is a global leader in providing healthcare information. Through our numerous product lines – Medi-Span, SKOLAR, Clin-eguide and Facts & Comparisons – professionals have access to immediate, trusted information at the point of care to help them make the best medical decisions for their patients.

Wolters Kluwer Health fully endorses the recommendations noted by NCPDP in their response, especially in the areas of versioning and pre-emption.

Wolters Kluwer Health fully endorses the recommendation of NCPDP's SCRIPT and Telecommunications Standards for the transmission of a prescription and claim between parties in the Medicare Part D Drug Program.

We will limit our comments to the areas that we are most familiar with in the e-prescribing process, the vocabularies and terminologies, and the content of the messaging.

**I. Background**

**Table of NCVHS recommendations compared to the Standards in the NPRM (F.R. Page 6262)**

**Wolters Kluwer Health Response:**

We are pleased that formal recommendations for RxNorm and drug-drug interaction information were not included in the NPRM at this time.

The RxNorm terminology is suitable to test as a drug terminology in the pilot tests to see if it can meet the prescriber's intent of the drug to be ordered/dispensed. To date, the RxNorm terminology is untested and there has been no opportunity to adopt or implement it until very recently in the private sector.

As to the drug-drug interaction information, there is a place in the electronic interchange of a prescription between parties to note that an interaction has been identified, yet the prescription should still be dispensed. However, there is not a need to include all the supporting documentation for that interaction between parties. As standards are identified, we need to make sure that they support the interchange of a prescription between parties, not what should be done within the prescriber system in the act leading up to and through the creation of a prescription.

**Drug Information (F.R. Page 6264)**

*We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*

**Wolters Kluwer Health Response:**

Requiring the electronic interchange of drug labeling and drug listing information should not be part of the e-prescribing process. The e-prescribing process should be limited to the exchange of an electronic drug order and patient medical and drug information. The e-prescribing process should not include the exchange of electronic drug referential data. Access to referential electronic drug information should be part of the overall physician practice management system and access to this type of information should not hinder the exchange of e-prescribing data. The availability and type of drug information made available to the prescriber should be determined by the prescriber's practice setting and individual needs.

**Medical History (F.R. Page 6264)**

**Wolters Kluwer Health Response:**

We support the need for a standardized allergy terminology. Through our testimony to NCVHS and subsequent discussions, we asked for an allergy terminology standard to be identified so that we can map our proprietary terminologies to the standard terminology to facilitate interoperability and the exchange of allergen information between and across systems.

**H. Summary of Status of Standards for an Electronic Prescription Drug Program (F.R. Page 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**Wolters Kluwer Health Response:**

We support the adoption of e-prescribing as a stepping stone to a full EHR. We can see no benefit to impeding the momentum driving the adoption of e-prescribing nor the development and implementation of standards for e-prescribing. E-prescribing and EHRs can exist both in an integrative and independent fashion. EHR is very broad and may be implemented in different timeframes and may be driven by different business and clinical needs. E-prescribing is available today and is being used in many clinical settings. As functionality is available, it should be incorporated into the whole continuum of care; but do not postpone implementation of the parts that are available today.

**IV. Regulatory Impact Analysis (F.R. Page 6268)**

*We invite public comment on our expectations for prescriber participation.*

**A. Overall Impact (F.R. Page 6268)**

*We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.*

**Wolters Kluwer Health Response:**

In the third column of page 6268, we caution that the advantages and benefits noted for “e-prescribing” and “e-prescribing programs” relate more to the electronic system to capture patient history, medication history, and medications; to run electronic, real-time alerts; and to access on-line information resulting in better care than the actual process and benefits of transmitting the drug order electronically between two sites as noted in the e-prescribing definition on page 6273.

**F. Impact on Others (F.R. Page 6271)**

*We have no estimates for these types of costs and invite public comment from healthcare information technology vendors and others on the impact of e-prescribing.*

**Wolters Kluwer Health Response:**

Other costs not noted in this section include the cost of the knowledge-base providers to incorporate mappings of their vocabularies to standardized vocabularies and distribution and maintenance of these mappings for terminologies noted in future regulations. Additionally, the cost for all sites to incorporate these "standardized" terminologies will require additional work for pharmacy system vendors, pharmacies, and e-prescribing/EMR system vendors.

**Conclusion**

Wolters Kluwer Health supports this electronic prescribing initiative and offers its assistance to CMS with issues that relate to terminologies as noted in the MMA.

Sincerely,

Karen Eckert
Director, e-Prescribing, Regulations, and Standards
Wolters Kluwer Health
Medi-Span product line
8425 Woodfield Crossing Blvd, Suite 490
Indianapolis, IN 46240
317/735-5308
keckert@drugfacts.com

**Submitter :** **Mrs. Alissa Fox** **Date: 04/05/2005**

**Organization :** **Blue Cross Blue Shield Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

**Issues**

Background

Attention: CMS-0011-P, Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people ? nearly one-in-three Americans ? among them approximately one million beneficiaries in Medicare Advantage.
BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries ? and also help slow the rate of growth in spending ? by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.
First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard. CMS should allow a period of pilot testing before final adoption of standards ? as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange ? and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).
? BCBSA supports CMS choices of ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, many commercial and proprietary e-prescribing systems currently do not use these standards. It will take time to develop and deploy software that uses these standards, time to test these standards, and time to identify and correct any problems integrating 270/271 and NCPDP standards.
?Performance testing is particularly important for the 270/271 standards because relatively few providers are now originating 270 transactions for claims. For example, 2004 data on HIPAA transactions from Blue Cross and Blue Shield Plans? national accounts and traveling members show that 270 transactions comprised less than 2 percent of total HIPAA transactions.
?For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

In addition to changing the compliance date, BCBSA urges CMS to make two other important changes:
?Adopt a broader view of preemption that federal law preempts any state law. CMS?s narrow interpretation of preemption could make e-prescribing administratively difficult for providers, pharmacies, and administrators.
? Follow the NCVHS recommendation that an organization?s internal communications not be covered by the rule. CMS?s proposal unnecessarily regulates entities? internal processes, thus raising the administrative burden of supporting e-prescribing.
We appreciate the opportunity to offer these comments, which we strongly believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit. Please see attached.

CMS-0011-P-60-Attach-1.DOC

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

**Blue Cross Blue Shield Association Comments on**
**"Medicare Program: E-Prescribing and the Prescription Drug Program"**
**Proposed Rule**
**NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)**
**CMS-0011-P**

**April 5, 2005**

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific "issue identifier" that precedes the section: **Background;** and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on February 4, 2005.

## I. Background

**State preemption (Page 6258)**

**Proposed Rule:** The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

**Issues:** Variations in state rules and regulations are ubiquitous. As explained in a separate letter "Comments on E-Prescribing of Drugs and Preemption of State Laws," BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

**BCBSA Recommendation:** BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

**Criteria for determining foundation standards (Page 6261)**

**Proposed Rule:** The MMA permits HHS to adopt standards as final without pilot testing where the Secretary can determine there is "adequate industry experience" with the standard. The MMA did not define "adequate industry experience." CMS has proposed the following criteria to assess adequate industry experience:

- American National Standards Institute (ANSI) accredited;
- Generally has been implemented in multiple e-prescribing programs with more than one external partner by entities to which the final standard will apply; and
- Recognized by key industry stakeholders as the industry standard.

**Issues**: We believe that these criteria are necessary – especially ANSI accreditation – but not sufficient to assess adequate industry experience. The HIPAA transaction experience demonstrates that systems and processes vary greatly, especially around key vendor products. Therefore, implementation in "multiple" e-prescribing programs is no guarantee that a standard can go without testing in all settings; for example, systems that work well for a chain pharmacy model may not work well for independent pharmacies or for mail order pharmacies.

**BCBSA Recommendation:** CMS should seek additional recommendations from stakeholders on how to assess adequate industry experience. CMS's view that there is adequate industry experience for the proposed foundation standards – a view that we question – is indicative of the need for added criteria.

**Identifiers (Page 6262)**

**Proposed Rule:** CMS is considering requiring the use of the national provider identifier (NPI) as the provider identifier for an e-prescription under Medicare Part D. The NPI timetable calls for HHS to begin accepting applications from providers for identifiers after May 23, 2005. Use of the NPI is mandatory starting May 23, 2007 (2008 for small health plans).

**Issue:** At this time, it appears that the NPI will not be universally available for use by January 2006. For HIPAA NPI implementation purposes, industry has proposed a "workaround" that would allow transactions to carry both the old identifier and the new NPI. However, provider and vendor systems that send billing information to the Plans may not be able to carry both the legacy identifier and the NPI by January 2006.

Plans that did not expect to have to be ready to process the NPI until 2007 may begin to receive transactions with the NPI as the only identifier and other transactions with a non-NPI identifier. Depending on the source of the transaction, plan systems would have to process the transaction using the NPI or a legacy identifier – running and maintaining duplicate systems for the interim period. Plans must be given sufficient time to migrate providers from their legacy identifiers to the providers' new NPI. Additionally, the NPI does not support the necessary transmission routing functions of electronic prescribing identifiers. Current identifiers allow for individual prescriber identification and multiple service locations. A single identifier solution for this shortcoming must be developed, assessed and tested.

**BCBSA Recommendation:** BCBSA urges that CMS move back the January 1, 2006 compliance date to permit additional time for pilot testing and implementation. This would have

the added benefit of avoiding the issues created by an early implementation of the NPI for e-prescribing.

We note that the Workgroup for Electronic Date Interchange (WEDI) recommended in a September 30, 2004 letter to Secretary Tommy Thompson that no successful implementation of the NPI could occur in less than 18 months from the time the NPI is available for use, and that no full-scale implementation should be undertaken without pilot testing the NPI.[1] We would support pilot testing use of the NPI in the e-prescribing context.

**Formulary and medication history standards (Page 6263)**

**Proposed Rule:** The NCVHS determined that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer Protocols established by RxHub. On the basis of this determination and other criteria revealed in the proposed rule, CMS is proposing to adopt other standards currently under development by NCPDP as foundation standards.

**Issue:** Many Plans that intend to offer Part D benefits use commercial or proprietary formulary and medication history messaging protocols dissimilar to those that will be balloted by NCPDP. Thus, adequate industry experience is lacking.

**BCBSA Recommendation:** CMS should adopt the formulary and medication history standards currently being balloted by NCPDP as initial standards to pilot test and not as foundation standards for required use beginning January 1, 2006.

**Proposed foundation standards (Page 6264)**

**Proposed Rule:** CMS proposes to apply the "adequate industry experience" exception to specific standards regarding prescription transmissions between prescribers and dispensers and eligibility inquiries between dispensers and payors and prescribers and payors (NCPDP SCRIPT Standard, Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5.1; and American Standards Committee (ASC) X 12N 270/271).

**Issue:** BCBSA supports using ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, industry does not have adequate experience because many current commercial and proprietary e-prescribing systems do not use the 270/271 standards. These e-prescribing systems generally provide eligibility information to the pharmacy using the NCPDP telecommunication standard. It will take time to make enrollee eligibility available to physicians using the 270/271 transaction: time for software development; time for deployment; and time to identify and correct any integration problems.

For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

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[1] *See* "WEDI NPIPAG Recommendations, August 26, 2004," Issues 1 and 3. A copy of this correspondence can be found at http://www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/093004NPIFinalEDJR.pdf .

Lack of adequate industry experience may be a particular issue for mail order pharmacies. Communicating eligibility and benefit status to and from a dispensing pharmacy via the NCPDP telecommunications standard is currently a HIPAA required transaction standard for communications with retail pharmacies. But in mail order pharmacies, prescriptions generally arrive via fax and are entered into the mail-order pharmacy's automated fill-order system. Eligibility is determined by checking against enrollee information provided by a plan directly to the mail-order pharmacy and not through an on-line inquiry system built to the NCPDP Telecommunications Standard. These processes operate on computer programs written to code not interoperable with e-prescribing software.

**BCBSA Recommendation:** While BCBSA supports the selection of specific appropriate standards for e-prescribing functions, we urge CMS to support a period of pilot testing (for at least one year) to ensure that the 270/271 standards will perform as desired when integrated into an e-prescribing systems with the NCPDP Telecommunication standards. Also, we urge CMS to provide for an implementation period (the statutory timetable would suggest 24 months) that gives plans sufficient time to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

## II. Provisions

### Definitions (Page 6265)

**Proposed Rule:** CMS proposes the following definition:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

**Issue:** The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

**Recommendation:** BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

### Communication in closed networks (Page 6265)

**Proposed Rule:** CMS would require e-prescribing communications internal to an organization be communicated in compliance with the adopted NCPDP Script standards for e-prescribing for Part D drugs. The NCVHS had recommended that organizations that conduct e-prescribing internally should not be required to convert to the standards to be adopted by CMS for Medicare Part D for prescription communications within their enterprise. CMS notes that the NCVHS

recommendation differs from the HIPAA transaction rule requirement that a "covered entity" conducting a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard HIPAA transaction.

**Issue:** BCBSA is concerned with CMS' decision not to follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. BCBSA's general approach to health information technology is that transaction rules should not dictate internal processing but should ensure standardizing the interfacing between differing organizations' systems for market interoperability.

**BCBSA Recommendation:** CMS should follow the recommendations of the NCVHS and recognize that the exchange of prescription information within the same enterprise is outside the scope of the MMA requirements.

**Backward compatibility (Page 6267)**

**Proposed Rule**: HHS is proposing to consider waiving notice and comment rulemaking when updates or newer versions of standards are "backward compatible" (i.e., entities using the newer version would be able to complete transactions with entities using the the previous version). In this case, CMS would likely permit the version that was previously adopted and the new version as equally compliant at the same time.

**Issue:** In general, an entity using the older version of a standard cannot process the newer version without further system changes, such as the addition of translation software – even when the newer version does not include substantive changes such as new functions. True backward compatibility occurs when the entity adopting the new version pays for the translation software. However, the CMS definition of backwards compatibility could be construed as absolving the entity adopting the new version of the obligation of paying for that translation software, thus inadvertently penalizing entities that choose to keep the previously adopted standard.

**BCBSA Recommendations:** CMS should make clear that the obligation to produce transactions that an entity with a previously adopted versions can process lies with the entity that chooses to migrate to the newer version. CMS should not find backward compatibility where no provision has been made in the standard to ensure that entities with previously adopted versions can process those transactions sent from entities using newer versions.

**Linking e-prescribing standards updates to HIPAA standards updates (Page 6267)**

**Proposed Rule:** CMS proposes to coordinate the updating process for those e-prescribing standards that are also HIPAA transaction standards.

**Issue:** Linking the e-prescribing standard update to the HIPAA standards update would provide administrative simplicity for CMS and reduce the compliance burden for the affected industries and covered entities.

**BCBSA Recommendation:** BCBSA supports having the e-prescribing standards updates tied to the HIPAA updates. This allows entities to monitor one point for future proposed changes. It also avoids getting HIPAA and e-prescribing out of synch and into conflicting requirements.

**Compliance date (Page 6267)**

**Proposed Rule:** CMS proposes making compliance with the e-prescribing standards proposed in this rule mandatory on Part D sponsors and MA/PD plans as of January 1, 2006.

**Issue:** BCBSA believes that January 2006 is not a reasonable compliance date for implementation of these proposed new foundation standards See “Proposed foundation standards” above

**BCBSA Recommendation:** See “Proposed foundation standards” above.

**Submitter :** **Mr. John Jones** **Date: 04/05/2005**

**Organization :** **Prescription Solutions**

**Category :** **Other Health Care Provider**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-0011-P-61-Attach-1.DOC

PacifiCare®

April 5, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P,
P.O. Box 8014,
Baltimore, MD 21244-8014.

RE: CMS-0011-P

Dear Sir or Madam:

On behalf of PacifiCare Health Systems, Inc. (PHS), I am responding with comments on the Notice of Proposed Rule Making for the Medicare electronic prescribing program.

PacifiCare is one of the nation's largest consumer and health services organizations, offering groups and individuals, including Medicare beneficiaries, a variety of consumer-driven health care and insurance products. PacifiCare currently serves some 700,000 Medicare beneficiaries enrolled on our Medicare Advantage plan – Secure Horizons – in eight western states. We have been participating in the Medicare risk program since its inception in the mid-1980s. Our wholly owned subsidiary, Prescription Solutions, provides comprehensive pharmacy benefit management services to our Medicare and commercial members as well as members of other external clients, serving over five million lives in total.

We greatly appreciate the opportunity to review these documents and provide commentary. We look forward to working with the Agency to implement the MMA.

If you have any questions, please contact me at (714) 226-3697.

Sincerely,

Steve Tucker,
Vice President
Regulatory Affairs

SMT:jlh

Attachment: Detailed Comments on CMS 0011-P

# Medicare Part D Commentary

CMS-0011-P

Medicare Program
E-Prescribing and the Prescription Drug Program

Submitted by
PacifiCare Health Systems
and Prescription Solutions

**OVERVIEW:**

PacifiCare appreciates the ability to provide comment on the proposed rule for the Medicare Program; E-Prescribing and the Prescription Drug Program published in the Federal Register on February 4th, 2005.

PacifiCare commends the Centers for Medicare & Medicaid Services (CMS) for actively developing and promoting electronic prescribing. We agree that electronic health record frontier holds the promise of reducing medical errors and vastly improving patient safety. We also recognize the work of the National Committee on Vital Health Statistics (NCVHS) and believe the Committee's initial recommendations to the Secretary helped to provide a framework for the e-prescribing environment.

The statute calls for the establishment of pilot programs beginning in 2006 to test the emerging electronic prescribing standards and we strongly support this requirement. PacifiCare was an early supporter of e-prescribing understanding the fundamental and unique benefits that this technology offers. We also acknowledge that for industry wide adoption to be successful, the infrastructure must be appropriately planned and implemented according to the real world environment. Finding the right balance for accelerated adoption of this new platform and ensuring success, in light of enormous modifications taking place with the new Part D benefit, will be a challenge and will require flexibility by CMS while plan sponsors develop each of the necessary component programs for successful implementation of the drug benefit in 2006. We believe that the pilots recommended by the Medicare Modernization Act (MMA) will provide the testing phase necessary to validate assumptions and negate the possible introduction of unanticipated problems. Therefore, it will be critical to allow the pilot programs to be completed prior to introduction of any broad e-prescribing capability. As with any new innovation, especially one steeped in an information technology function, intended solutions need to be confirmed prior to finalizing protocols.

**I Background**

**"BACKGROUND"**

**Compliance Date**

The Secretary proposes January 1, 2006 as the compliance date for the proposed foundation standards. We believe that the proposed timeline for the implementation of any e-prescribing standard by January 1, 2006 is operationally unfeasible and national implementation should be delayed.

After attending CMS open door forums on the MMA drug benefit and asking direct questions of CMS staff regarding the proposed e-prescribing compliance date, PacifiCare understands and has relied on the representation that the compliance date would only apply to those companies having e-prescribing programs in place on or after that date. It is also our understanding that there is no requirement that a company create a fully operational e-prescribing capability for the January 1, 2006 date. Indeed, the anticipated pilot programs intended to provide the experience and detail necessary to create the e-prescribing final standards will not have begun until on or after that date.

Additionally, health plans considering Part D participation have begun tasks associated with the annual contracting process. These activities reflect the requirements contained in the final Title I & II regulations and components integral to the Medicare Advantage (MA) and Prescription Drug Plan (PDP) application process. The timeline set forth by CMS for completion of the MA or PDP application requires that plans submit finalized participating pharmacy networks no later than July 15, 2005. In order to meet these strict deadlines, PacifiCare has initiated the overall contracting of the provider networks essential in meeting the Part D *Standards for Convenient Access* requirements.

The extremely aggressive implementation timeline proposed for e-prescribing foundation standards provides insufficient time necessary for encompassing the operational tasks associated with communicating contractual requirements to downstream providers. The activities involved with provider network contracting are resource intensive and time consuming, especially with the advent of a new product offering combined with the size of the regional pharmacy networks. Given that the e-prescribing regulations will not be finalized with adequate time to be incorporated into the current contracting cycle, we urge CMS to include the final provisions in the pilot testing phase.

**Initial Standards Versus Final Standards**

While the Secretary is permitted under the statute to pre-empt the pilot testing of components if sufficient real-world experience exists, we believe that by and large, e-prescribing is still in the infant stage and that all proposed standards should be tested in the pilot programs prior to nationwide roll-out. We have noted the observations made by the Secretary for the accelerated advancement of this technology as a step towards embracing a full electronic health record.

However, moving too quickly with mandatory standards may compromise overall prescriber participation and diminish the benefits associated with this endeavor.

The true e-prescribing environment is a recent phenomena only being credibly established over the last two to three years. The majority of e-prescribing studies have been conducted under optimal test site conditions and supported with resources to ensure success. Given that less than 10% of doctors currently use electronic prescribing, coupled with the multifaceted issues that impact provider use of new information technologies in the office setting, it is critical that e-prescribing be tested and validated prior to wide-spread implementation.

**State Preemption**

PacifiCare believes that adoption of unified e-prescribing standards through appropriate and full federal preemption of state laws is essential to overall success of e-prescribing in the health care industry. The Federal government and the States have distinct roles in relation to e-prescribing. While dispensers are ultimately responsible for ensuring the validity and authenticity of prescriptions under state statutes, prescribing requirements are controlled by state boards of pharmacy and the U.S. Department of Justice Drug Enforcement Administration (DEA).

There are state-to-state variations relating to prescribing requirements and the DEA currently requires Schedule II controlled substances to be authorized by the prescriber with a handwritten signature. Additionally, the NPRM notes that "The DEA has not yet made a ruling regarding the requirements for the electronic transmission of prescriptions for controlled substances." To reduce barriers and increase adoption of this new technology, we urge CMS to invoke preemption authority as afforded in the MMA.

**Anti-kickback Statute Safe Harbor and Stark Exception Section**

Numerous studies have identified economic barriers that retard physician adoption of e-prescribing. Without the support of these resources prescribers will not be incentivized to entertain this new tool, particularly as their organizations embrace various issues presented with the new Part D benefit. The protections afforded by the anti-kickback statute safe harbor are essential to the success of the e-prescribing program and we suggest that that the overall e-prescribing program be delayed, if the new exception for e-prescribing is not timely aligned with the e-prescribing initiative.

**Evolution and Implementation of an Electronic Prescription Program**

We believe that further articulation of these criteria is necessary and PacifiCare recommends that CMS clarify the subparts of the proposed definition for determining "adequate industry experience".

> • *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

PacifiCare recommends that CMS provide the basis for concluding that the "standard has been generally implemented by entities to which the final standard will be applied" including the sampling methodology, survey instruments, and the result authentication mechanism used to reach consensus of the assumptions used in this criterion.

> • *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

Pacificare suggests that CMS identify the methodology used to include entities as key industry stakeholders and the oversight process used to ensure that potential conflicts of interest do not pervade these decision making proceedings.

**Provider and Dispenser Identifiers**

The Secretary of Health and Human Services is required to adopt a national standard identifier (NPI) for health care providers under the administrative simplification provisions of the Health Insurance Portability and Accountability Act (HIPPA) of 1996. Although providers can begin to apply for an NPI in May 2005, most covered entities are not required to begin using the NPI until May 2007. Currently, physicians are identified by their DEA number. However, physicians who do not prescribe controlled substances may not hold a DEA number. Although the MMA does not expressly require the use of unique identifiers for prescribers or dispensers in e-prescribing, PacifiCare supports the enumeration of health care providers by this method. Some states have objected to the use of physician DEA numbers to identify prescribers for electronic adjudication of prescription claims and use of the NPI would help to eliminate this issue. However, if the NPI is not available for e-prescribing use, we suggest that CMS utilize federal preemption authority over state laws to allow the continued us of other unique prescriber identifiers, such as the DEA number.

**Formulary and Medication History Standards**

The proposed rule also states that, "the standards should be vendor neutral and technology independent". PacifiCare is concerned about the recommendations by some of the stakeholders in the industry to use RxHUB, a proprietary software program, as a basis for a foundation standard. The adoption of the RxHUB protocol as a foundation standard could potentially stifle competition between existing vendors and discourage new vendors from entering the market. We strongly urge CMS to reconsider the formal endorsement of RxHUB or clarify the involvement of this entity in the standard setting process.

**II. Provisions of the Proposed Regulation**

**"PROVISIONS"**

**Eligibility**

The Centers for Medicare and Medicaid Services (CMS) has proposed making the ASC X12 278 Healthcare Services Review a standard for use in the MMR Part D when ANSI can incorporate functionality for real-time prior authorization messages for drugs. PacifiCare believes that the

X12 format does not conform to the MMA intent that disclosure of information should "be on an interactive, real time basis" and that CMS should consider using the NCPDP 5.1 telecommunications standard which provides for this real-time interaction.

The ASC X12 278 Healthcare Services Review format is intended for use in a batch process incorporating more than one claim or request. As such, it is not currently usable in the standard real-time (single request) format. The majority of pharmacy claim payers and Pharmacy Benefit Managers (PBMs) are operating in a real-time environment. A requirement to use the ASC X12 178, even if modified for real-time use, would present a significant challenge to the real-time industry. The NCPDP 5.1 telecommunications standard, version 5.1, currently provides the ability to include information and details to support a prior authorization request. The MMA standard should be modified to include the option of using the NCPDP Telecommunication standard, version 5.1, as an option for drug related prior authorization requests.

PacifiCare recommends that until the ASC X12 278 has incorporated real-time functionality, and has been adequately piloted and used in production in the provider and payer communities, it should not be a required standard. Alternately, CMS should allow providers and payers to use the NCPDP 5.1 Telecommunication Standard where applicable until such time as an acceptable industry standard can be defined.

**Submitter :** **Dr. James Scully** **Date: 04/05/2005**

**Organization :** **THE AMERICAN PSYCHIATRIC ASSN.**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

**Issues**

Background

See Attachment

Provisions of the Proposed Regulation

See Attachment

Regulatory Impact Analysis

See Attachment

Collection of Information Requirements

See Attachment

CMS-0011-P-62-Attach-1.DOC

CMS-0011-P-62-Attach-2.DOC

American Psychiatric Association

1000 Wilson Boulevard
Suite 1825
Arlington. VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org

May 3, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

**RE: Medicare Program; E-Prescribing and the Prescription Drug Program**
**CMS-0011-P**

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

## I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

### A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf computer software. Instead, much of the available software is proprietary and uses

[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
>
> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
>
> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded voice messages, if relayed elsewhere, are also covered by this law. If electronically

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

### B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-prescribing. Compuware Corporation, Microsoft and Washington Publishing Company

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example. Instead they work solo or in small group practices that do not enjoy the ability to spread

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: **"**HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year.
Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

### C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the Office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had

[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

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[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006. [22]

**D. E-prescribing and Federal Grants**

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

**E. Manipulation of Physicians' Prescribing Choices**

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

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[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

## II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins." [28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

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[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

[30] NCPDP is accredited by the American National Standards Institute (ANSI).

[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

> 1. "Fill status notification" and RxNorm clinical drug terminology functions of NCPDP SCRIPT. (RxNorm provides links from clinical drugs' names to their active ingredients, components and most brand names.);[34]
>
> 2. Situational data elements and proper usage of functional acknowledgements of ASC X12N 270/271;[35]
>
> 3. Structured and codified *signatura* (SIGs) for patient instructions; and[36]
>
> 4. National prescriber identifiers (NPIs) need to be chosen and issues dealing with elements of prescriber location and connection to individual prescribers should be part of pilot testing.[37]

NCVHS also recommended pilot tests to evaluate the economic and quality-of-care impacts of automating prior authorization communications. Prior authorizations will be a major utilization management tool for formularies of Medicare Part D plans, as of

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[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

[34] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.6.

[35] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.8.

[36] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.10.

[37] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.12.

January 1, 2006. If the prior authorizations are not processed smoothly, patients will have difficulty getting continuous prescription coverage on their drug regimens.

Pilot-testing the proposed standards would confer several essential advantages for psychiatrists and their patients. If pilot-testing is done in 2006, results would be evaluated, then the final standards would not be published until April 1, 2008.[38] This would have the beneficial effect of moving the effective date for compliance with the standards into a more manageable time frame, instead of rushing it to January 1, 2006. After all, this date is only a few months after the proposed rule will be finalized.

For pilot tests to be conducted in 2006, initial standards must be adopted no later than September 1, 2005.[39] However, CMS proposes to adopt three standards as final without any pilots, on the basis that they meet CMS' criteria for having "adequate industry experience." They are not proposing to adopt any initial standards that would then require pilot tests. According to NCVHS, fewer than 3% of all prescriptions are written by prescribers using an integrated e-prescribing system of some type, presumably not all with the proposed final standards. A portion of those are in the VA hospital system, which uses integrated medical records and prescribing systems with its own data-transmission standards and software that is in the public domain.

Of course, CMS is aware of the widespread use of other standards within the federal healthcare system. CMS emphasized in an Executive Summary of July 2004 that "(t)here have been considerable efforts by HHS, DoD, and VA to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector."[40] CMS has lauded VA's healthcare informatics systems and suggested that they could transfer into the public sector. Moreover, their software is in the public domain, so it is more accessible than proprietary copyrighted software for

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[38] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[39] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[40] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: ". . . As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector. Additionally, the Public Health Information Network (PHIN) and the National Electronic Disease Surveillance System (NEDSS), under the leadership of the Centers for Disease Control and Prevention (CDC), have made notable progress in development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and health information exchange. With HHS support, Health Level 7 (HL7) has also created a functional model and standards for the EHR." Retrieved March 29, 2005: http://www.healthpolicyohio.org/OHHIT/NHII_2004/HealthITStrategicFrameworkExecSummary.htm

companies that wish to develop products with it.[41] For these reasons, it is unclear what stands in the way of CMS adopting at least one standard in use within the federal system as an initial standard and pilot-testing it.

NCVHS noted in its letter to CMS that a standard from Health Level Seven, Inc. (HL7), is commonly used for medication orders in hospitals and clinical pharmacies and advocated coordinating HL7 with NCPDP SCRIPT. Many staff model HMOs and the VA use HL7 internally for most drug orders.[42],[43] In July 2004, HL7 issued a press release announcing that the Board of Directors "had unanimously approved the Electronic Health Record System Functional Model (EHR-S) to move forward as a Draft Standard for Trial Use (DSTU). The EHR Draft Standard can now be registered with ANSI, beginning the draft standard's trial period of up to 24 months. . . An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records."[44]

Given their widespread use, it would appear that at least some of these aforementioned standards would meet the test for "adequate industry experience" and, at least, be under consideration for status as initial standards for pilot testing. However, none of these standards appear to be under consideration by CMS at this time for adopted as initial standards and this must be done by September 1, 2005, to be pilot tested in 2006.

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[41] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: "The VA's report, 'Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities' (Attachment 2), also highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain. These technologies may be suitable for transfer to rural and medically underserved settings. VA's primary health information systems and EHR (VistA and the Computerized Patient Record System [the current system] and HealtheVet-VistA, the next generation in development) provide leading government/public-owned health information technologies that support the provision, measurement, and improvement of quality, affordable care across 1300 VA inpatient and ambulatory settings. . . The VA is also incorporating the CHI approved standards into its next-generation HealtheVet-VistA. . . Finally, the VA's health information technologies, such as bar code medication administration, VistA Imaging, and telehealth applications, provide the VA with exceptional tools that improve patient safety and enable the increasingly geographically dispersed provision of care to patients in all settings."

[42] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265: "Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy."

[43] Consolidated Health Informatics: "Standards Adoption Report: Messaging Standards: Retail Pharmacy Transactions;" p. 5. Retrieved March 22, 2005: http://www.whitehouse.gov/omb/egov/documents/domain3.doc

[44] Health Level Seven, Inc. (HL7) Press Release: "Board of Directors Unanimously Approves EHR for Draft Standard Status;" July 27, 2004.

Presumably, any change to existing standards would require legislation to revise or add language to 42 C.F.R. Sec. 423.160. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) pre-empts state laws and prohibits them from enacting legislation that contravenes federal provisions as to e-prescribing standards.[45] So, once federal law mandates specific standards, state law cannot alter or affect physicians' compliance requirements.

APA's view is that it is unwise to forego a pilot test of the standards and technologies using them that is likely to bring to light glitches more easily worked out on a small scale than on a wide scale. It is particularly clear that integrated e-prescribing systems that communicate among prescribers, dispensers and health care plans have not been in widespread use across a variety of clinical settings. For that reason alone, it is unclear precisely what practical issues need to be resolved. Further, the extensive MMA requirements demands solid, seamless integration of multiple messaging, data translation, data transfer and data access functions using at least three standards, as well as file transfer protocols such as RxHub. The integration of these standards and technologies using them has yet to be accomplished and fully tested in the field, to ensure compliance with MMA and HIPAA. Moreover, there is the issue of how software incorporating these standards will interface with web-based applications and a variety of hardware combinations.

Unless and until sufficient pilot tests are done with physicians under real-life clinical conditions to identify and resolve e-prescribing problems, CMS' laudable goals will be impeded. More importantly, once physicians begin to experience difficulties using e-prescribing systems because functionality has not yet been perfected, their frustration may well reduce or cease the use of e-prescribing altogether. In addition, negative publicity about roadblocks in the systems will deter many others from adopting e-prescribing.

Apart from time they need to properly evaluate systems against their needs, physicians also require time to become familiar with the systems, alter practices to accommodate new processes and train staff. Feedback from pilot testing will assist companies in developing physician and patient-centered products, services, training and educational materials. This will ultimately make e-prescribing more attractive and effective across various dimensions, including the enhancement of patient outcomes.

The transition to using new technologies and equipment will take physicians' time and energy. This may be more of a demand for those who do not currently own a computer. To rush this process is to increase the risk of medication errors and suboptimal patient outcomes. Those results would contravene one of CMS' primary goals for advancing e-prescribing, which is to reduce negative patient outcomes due to errors in traditional prescribing systems.

[45] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

Another positive result of pilot-testing is that it would move the compliance date away from January 1, 2006. That would give psychiatrists time to plan for the substantial financial outlay for an e-prescribing system. The expanded time window will also allow psychiatrists to apply for federal matching grants for e-prescribing systems. These grants will not be funded until 2007. In addition, legislators will get more time to implement the projected new Safe Harbor and the new Stark II exemption that are intended to allow physicians to accept non-monetary assistance for e-prescribing systems without violating current federal laws.

***Recommendations:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards with physicians, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

## III. "PROVISIONS:" The Secretary's Proposed Effective Date of January 1, 2006, for E-Prescribing Compliance is Premature and Carries Adverse Implications

### A. Prematurity of the Proposed Effective Date

The HHS Secretary has the discretion to choose a more practical and appropriate effective date for e-prescribing compliance than January 1, 2006, and APA urges him to do so. This date is premature for several reasons and adopting it will produce adverse effects for physicians and their patients. It will also discourage psychiatrists and other physicians from adopting e-prescribing, until many technological and practical issues area resolved. The following are some of the reasons why January 1, 2006, is not a judicious choice as an effective date for compliance with e-prescribing:

1. January 1, 2006, is the same effective date for transition of dually eligible Medicare/Medicaid patients into Medicare, which will already be burdensome for physicians and patients;

2. CMS admits that it may not be possible to issue a National Provider Identifier (NPI), as planned, for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline. In addition this date is earlier than the current HIPAA compliance date for using an NPI for covered e-prescribing transactions;

3. January 1, 2006, is premature and does not synchronize with the availability of federal matching grants for physicians' e-prescribing systems, which begin being funded in 2007;

4. January 1, 2006, does not allow sufficient time to finalize a new Safe Harbor and a new Stark II exception, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems, without rendering them vulnerable to federal prosecution under current anti-kickback and Stark II laws; and

5. CMS notes that it may not be possible to issue a National Provider Identifier (NPI) for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline, which would be earlier than the current compliance date for HIPAA covered transactions. Thus, it would be impossible for physicians to be in compliance in using a HIPAA-required NPI, if they are not issued one before the deadline. E-prescribing transmissions will make physician-prescribers covered entities for HIPAA compliance. We believe that psychiatrists should not be legally mandated to use an NPI until it exists and that confusion about which identifier will be required should be resolved prior to any compliance effective date. Alternative identifiers for e-prescribing could be the physician's medical license number, DEA number, EIN or Social Security number.

***Recommendation:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

**B. "IMPACT ANALYSIS:" Privacy Concerns**

Patient privacy is particularly critical in ensuring high quality psychiatric care. Psychiatrists are also rightly concerned about how e-prescribing technologies, such as web-based portals, may compromise their patients' privacy, and hence impair the foundation of trust that is the core of the psychiatrist-patient relationship. It is not until pilot tests sort out these and other potential issues that psychiatrists are likely to gain sufficient comfort with adopting e-prescribing techniques. We remain concerned about the inadequate safeguards to potential breaches in the security of identifiable patient information, through electronic transmissions and databases. It is critically important to ensure the security of and to prevent hacking into electronic systems, especially as regards the confidentiality of patients' medications. As a consequence, CMS must address this e-prescribing issue directly.

Regrettably, confidentiality is too often overlooked as an essential element of high-quality health care. Out of fear of disclosure, some patients simply will not provide the full information necessary for successful treatment. Others refrain from seeking medical care or drop out of treatment, in order to avoid any risk that their records are not entirely private. With regard to e-prescribing and its use of the internet and other electronically accessible databases, this fear may be heightened for some psychiatric patients, especially those with paranoid features to their illness. A psychiatrist is hard-pressed to assure a patient about confidentiality when there are headlines about databank breaches.

A pharmacist can legally contact a list of his or her pharmacy's patients, who have been prescribed certain drugs, in order to inform them about alternative drug therapies. A pharmaceutical company can pay the pharmacist to do this, though it cannot directly obtain patient information and contact patients. This allows pharmaceutical companies to indirectly promote targeted drugs to patients. Also, pharmacies can promote their own financial interests by urging a patient to use medications that are more profitable for the pharmacy. Marketing communications do not necessarily need to disclose these compensation arrangements.

APA believes that patients need to be certain that there will be no downstream release of information to marketers and that the security of their health records will be safeguarded. A strong CMS policy to that effect would give vendors a clear message of CMS' expectations, as this applies to e-prescribing systems and security. It is critically important that CMS respond to the e-prescribing security concerns of psychiatrists, as well as all physicians, and their patients.

As mentioned above, mental health records are particularly sensitive to release and disclosure, partly due to the unfortunate, pervasive social stigma about mental disorders. A patient might not want family, neighbors, or even a postal delivery person to see a postcard from a pharmacy suggesting that he or she is on psychotropic medication. Such communications could undermine mental health care, as patients avoid or delay it, to avoid stigmatization.

## CONCLUSION AND RECOMMENDATIONS

APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing within the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach. Pilot testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. What may constitute "adequate industry experience" with standards within one context, i.e., intra-entity transmissions or within partial e-prescribing systems, may well not work as anticipated within a different environment. For instance, problems may arise when psychiatrists, or, indeed, any physicians, in a small group practice use a fully integrated e-prescribing system to communicate with managed care companies and external pharmacies using different systems.

Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings, will it be feasible to determine precisely which standards, process areas or technologies require adjustment. All standards to be used for e-prescribing must have the capability of being used within products that work seamlessly across different data-interchange platforms and among all entities involved in the prescribing process. Moreover, the standards ultimately adopted as final foundation standards to be embedded within software, used via web portals and within e-prescribing systems hardware must be efficiently inter-functional and meet the intended practical and legal requirements. It will take some time to discover how to perfect these systems and CMS must not foreshorten this process, or it will prove to ultimately be at the expense of patients.

Psychiatric patients on prescription psychotropics are especially vulnerable to delays, glitches, and errors that could be caused by premature adoption of standards, resulting in ineffective systems. Since medication adherence is already a serious issue for such patients, even delays of a day or two in receiving prescription fills could seriously and adversely affect them. It will be much easier to collect data, provide feedback loops, and create corrective interventions within a smaller pilot-test system of e-prescribing, than within a large one. Moreover, fewer physicians and patients will be negatively affected when something goes awry within a pilot test, than within a wider context of usage. It simply makes practical sense to evaluate a major change of this dimension on the prescribing mechanisms for physicians on a small scale, before expanding the process into a larger patient-care environment.

Successes within the pilot tests can then be used to encourage further adoption of e-prescribing, while physicians remain confident that obstacles to effective use will be resolved at the pilot stage, before they adopt the technologies. In this way, e-prescribing will become a more palatable alternative to physicians, who will have a more definitive set of reasons to adopt it, with solid evidence of its advantages and confidence in its practicality. Physicians also require reassurance from CMS that policies will be adopted

that send a clear message to companies that commercial messages and design bias in software and hardware for e-prescribing will not be tolerated.

Pilot testing in 2006 will automatically advance the effective date for compliance, which has the added benefit of allowing sufficient time to promulgate the new Safe Harbor and new Stark II exception that give physicians the freedom to accept assistance in establishing e-prescribing systems. It will also be in line with the timeframe that will ensure physicians' access to federal grants to underwrite such systems. APA's specific recommendations are reiterated, below:

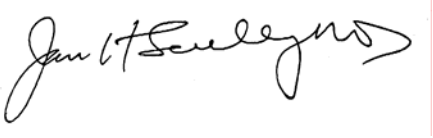
***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor for physicians to freely accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

***Recommendations-Pilot Testing:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

***Recommendation-Effective Date:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

American Psychiatric Association

1000 Wilson Boulevard
Suite 1825
Arlington. VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org

May 3, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

**RE: Medicare Program; E-Prescribing and the Prescription Drug Program**
**CMS-0011-P**

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

## I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

### A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf computer software. Instead, much of the available software is proprietary and uses

[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
>
> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
>
> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded voice messages, if relayed elsewhere, are also covered by this law. If electronically

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

### B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-prescribing. Compuware Corporation, Microsoft and Washington Publishing Company

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example. Instead they work solo or in small group practices that do not enjoy the ability to spread

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: **"**HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year.
Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

### C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the Office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had

[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

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[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006. [22]

**D. E-prescribing and Federal Grants**

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

**E. Manipulation of Physicians' Prescribing Choices**

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

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[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

## II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins." [28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

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[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

[30] NCPDP is accredited by the American National Standards Institute (ANSI).

[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

> 1. "Fill status notification" and RxNorm clinical drug terminology functions of NCPDP SCRIPT. (RxNorm provides links from clinical drugs' names to their active ingredients, components and most brand names.);[34]
>
> 2. Situational data elements and proper usage of functional acknowledgements of ASC X12N 270/271;[35]
>
> 3. Structured and codified *signatura* (SIGs) for patient instructions; and[36]
>
> 4. National prescriber identifiers (NPIs) need to be chosen and issues dealing with elements of prescriber location and connection to individual prescribers should be part of pilot testing.[37]

NCVHS also recommended pilot tests to evaluate the economic and quality-of-care impacts of automating prior authorization communications. Prior authorizations will be a major utilization management tool for formularies of Medicare Part D plans, as of

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[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

[34] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.6.

[35] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.8.

[36] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.10.

[37] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson, p.12.

January 1, 2006. If the prior authorizations are not processed smoothly, patients will have difficulty getting continuous prescription coverage on their drug regimens.

Pilot-testing the proposed standards would confer several essential advantages for psychiatrists and their patients. If pilot-testing is done in 2006, results would be evaluated, then the final standards would not be published until April 1, 2008.[38] This would have the beneficial effect of moving the effective date for compliance with the standards into a more manageable time frame, instead of rushing it to January 1, 2006. After all, this date is only a few months after the proposed rule will be finalized.

For pilot tests to be conducted in 2006, initial standards must be adopted no later than September 1, 2005.[39] However, CMS proposes to adopt three standards as final without any pilots, on the basis that they meet CMS' criteria for having "adequate industry experience." They are not proposing to adopt any initial standards that would then require pilot tests. According to NCVHS, fewer than 3% of all prescriptions are written by prescribers using an integrated e-prescribing system of some type, presumably not all with the proposed final standards. A portion of those are in the VA hospital system, which uses integrated medical records and prescribing systems with its own data-transmission standards and software that is in the public domain.

Of course, CMS is aware of the widespread use of other standards within the federal healthcare system. CMS emphasized in an Executive Summary of July 2004 that "(t)here have been considerable efforts by HHS, DoD, and VA to adopt health information standards for use by all federal health agencies. As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector."[40] CMS has lauded VA's healthcare informatics systems and suggested that they could transfer into the public sector. Moreover, their software is in the public domain, so it is more accessible than proprietary copyrighted software for

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[38] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[39] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6258.

[40] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: ". . . As part of the Consolidated Health Informatics (CHI) initiative, the agencies have agreed to endorse 20 sets of standards to make it easier for information to be shared across agencies and to serve as a model for the private sector. Additionally, the Public Health Information Network (PHIN) and the National Electronic Disease Surveillance System (NEDSS), under the leadership of the Centers for Disease Control and Prevention (CDC), have made notable progress in development of shared data models, data standards, and controlled vocabularies for electronic laboratory reporting and health information exchange. With HHS support, Health Level 7 (HL7) has also created a functional model and standards for the EHR." Retrieved March 29, 2005: http://www.healthpolicyohio.org/OHHIT/NHII_2004/HealthITStrategicFrameworkExecSummary.htm

companies that wish to develop products with it.[41] For these reasons, it is unclear what stands in the way of CMS adopting at least one standard in use within the federal system as an initial standard and pilot-testing it.

NCVHS noted in its letter to CMS that a standard from Health Level Seven, Inc. (HL7), is commonly used for medication orders in hospitals and clinical pharmacies and advocated coordinating HL7 with NCPDP SCRIPT. Many staff model HMOs and the VA use HL7 internally for most drug orders.[42],[43] In July 2004, HL7 issued a press release announcing that the Board of Directors "had unanimously approved the Electronic Health Record System Functional Model (EHR-S) to move forward as a Draft Standard for Trial Use (DSTU). The EHR Draft Standard can now be registered with ANSI, beginning the draft standard's trial period of up to 24 months. . . An EHR standard is seen as one of the keys to supporting the exchange of information for clinical decisions and treatments, and can help lay the groundwork for nationwide interoperability by providing common language parameters that can be used in developing systems that support electronic records."[44]

Given their widespread use, it would appear that at least some of these aforementioned standards would meet the test for "adequate industry experience" and, at least, be under consideration for status as initial standards for pilot testing. However, none of these standards appear to be under consideration by CMS at this time for adopted as initial standards and this must be done by September 1, 2005, to be pilot tested in 2006.

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[41] U.S. Department of Health and Human Services, "Health IT Strategic Framework: Executive Summary;" July 23, 2004: "The VA's report, 'Approaches to Make Health Information Systems Available and Affordable to Rural and Medically Underserved Communities' (Attachment 2), also highlights its successful strategy to develop high-quality EHR technologies that remain in the public domain. These technologies may be suitable for transfer to rural and medically underserved settings. VA's primary health information systems and EHR (VistA and the Computerized Patient Record System [the current system] and HealtheVet-VistA, the next generation in development) provide leading government/public-owned health information technologies that support the provision, measurement, and improvement of quality, affordable care across 1300 VA inpatient and ambulatory settings. . . The VA is also incorporating the CHI approved standards into its next-generation HealtheVet-VistA. . . Finally, the VA's health information technologies, such as bar code medication administration, VistA Imaging, and telehealth applications, provide the VA with exceptional tools that improve patient safety and enable the increasingly geographically dispersed provision of care to patients in all settings."

[42] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265: "Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy."

[43] Consolidated Health Informatics: "Standards Adoption Report: Messaging Standards: Retail Pharmacy Transactions;" p. 5. Retrieved March 22, 2005: http://www.whitehouse.gov/omb/egov/documents/domain3.doc

[44] Health Level Seven, Inc. (HL7) Press Release: "Board of Directors Unanimously Approves EHR for Draft Standard Status;" July 27, 2004.

Presumably, any change to existing standards would require legislation to revise or add language to 42 C.F.R. Sec. 423.160. In addition, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) pre-empts state laws and prohibits them from enacting legislation that contravenes federal provisions as to e-prescribing standards.[45] So, once federal law mandates specific standards, state law cannot alter or affect physicians' compliance requirements.

APA's view is that it is unwise to forego a pilot test of the standards and technologies using them that is likely to bring to light glitches more easily worked out on a small scale than on a wide scale. It is particularly clear that integrated e-prescribing systems that communicate among prescribers, dispensers and health care plans have not been in widespread use across a variety of clinical settings. For that reason alone, it is unclear precisely what practical issues need to be resolved. Further, the extensive MMA requirements demands solid, seamless integration of multiple messaging, data translation, data transfer and data access functions using at least three standards, as well as file transfer protocols such as RxHub. The integration of these standards and technologies using them has yet to be accomplished and fully tested in the field, to ensure compliance with MMA and HIPAA. Moreover, there is the issue of how software incorporating these standards will interface with web-based applications and a variety of hardware combinations.

Unless and until sufficient pilot tests are done with physicians under real-life clinical conditions to identify and resolve e-prescribing problems, CMS' laudable goals will be impeded. More importantly, once physicians begin to experience difficulties using e-prescribing systems because functionality has not yet been perfected, their frustration may well reduce or cease the use of e-prescribing altogether. In addition, negative publicity about roadblocks in the systems will deter many others from adopting e-prescribing.

Apart from time they need to properly evaluate systems against their needs, physicians also require time to become familiar with the systems, alter practices to accommodate new processes and train staff. Feedback from pilot testing will assist companies in developing physician and patient-centered products, services, training and educational materials. This will ultimately make e-prescribing more attractive and effective across various dimensions, including the enhancement of patient outcomes.

The transition to using new technologies and equipment will take physicians' time and energy. This may be more of a demand for those who do not currently own a computer. To rush this process is to increase the risk of medication errors and suboptimal patient outcomes. Those results would contravene one of CMS' primary goals for advancing e-prescribing, which is to reduce negative patient outcomes due to errors in traditional prescribing systems.

[45] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

Another positive result of pilot-testing is that it would move the compliance date away from January 1, 2006. That would give psychiatrists time to plan for the substantial financial outlay for an e-prescribing system. The expanded time window will also allow psychiatrists to apply for federal matching grants for e-prescribing systems. These grants will not be funded until 2007. In addition, legislators will get more time to implement the projected new Safe Harbor and the new Stark II exemption that are intended to allow physicians to accept non-monetary assistance for e-prescribing systems without violating current federal laws.

***Recommendations:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards with physicians, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

## III. "PROVISIONS:" The Secretary's Proposed Effective Date of January 1, 2006, for E-Prescribing Compliance is Premature and Carries Adverse Implications

### A. Prematurity of the Proposed Effective Date

The HHS Secretary has the discretion to choose a more practical and appropriate effective date for e-prescribing compliance than January 1, 2006, and APA urges him to do so. This date is premature for several reasons and adopting it will produce adverse effects for physicians and their patients. It will also discourage psychiatrists and other physicians from adopting e-prescribing, until many technological and practical issues area resolved. The following are some of the reasons why January 1, 2006, is not a judicious choice as an effective date for compliance with e-prescribing:

1. January 1, 2006, is the same effective date for transition of dually eligible Medicare/Medicaid patients into Medicare, which will already be burdensome for physicians and patients;

2. CMS admits that it may not be possible to issue a National Provider Identifier (NPI), as planned, for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline. In addition this date is earlier than the current HIPAA compliance date for using an NPI for covered e-prescribing transactions;

3. January 1, 2006, is premature and does not synchronize with the availability of federal matching grants for physicians' e-prescribing systems, which begin being funded in 2007;

4. January 1, 2006, does not allow sufficient time to finalize a new Safe Harbor and a new Stark II exception, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems, without rendering them vulnerable to federal prosecution under current anti-kickback and Stark II laws; and

5. CMS notes that it may not be possible to issue a National Provider Identifier (NPI) for all "covered" dispensers and prescribers in time for a January 1, 2006, deadline, which would be earlier than the current compliance date for HIPAA covered transactions. Thus, it would be impossible for physicians to be in compliance in using a HIPAA-required NPI, if they are not issued one before the deadline. E-prescribing transmissions will make physician-prescribers covered entities for HIPAA compliance. We believe that psychiatrists should not be legally mandated to use an NPI until it exists and that confusion about which identifier will be required should be resolved prior to any compliance effective date. Alternative identifiers for e-prescribing could be the physician's medical license number, DEA number, EIN or Social Security number.

***Recommendation:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

**B. "IMPACT ANALYSIS:" Privacy Concerns**

Patient privacy is particularly critical in ensuring high quality psychiatric care. Psychiatrists are also rightly concerned about how e-prescribing technologies, such as web-based portals, may compromise their patients' privacy, and hence impair the foundation of trust that is the core of the psychiatrist-patient relationship. It is not until pilot tests sort out these and other potential issues that psychiatrists are likely to gain sufficient comfort with adopting e-prescribing techniques. We remain concerned about the inadequate safeguards to potential breaches in the security of identifiable patient information, through electronic transmissions and databases. It is critically important to ensure the security of and to prevent hacking into electronic systems, especially as regards the confidentiality of patients' medications. As a consequence, CMS must address this e-prescribing issue directly.

Regrettably, confidentiality is too often overlooked as an essential element of high-quality health care. Out of fear of disclosure, some patients simply will not provide the full information necessary for successful treatment. Others refrain from seeking medical care or drop out of treatment, in order to avoid any risk that their records are not entirely private. With regard to e-prescribing and its use of the internet and other electronically accessible databases, this fear may be heightened for some psychiatric patients, especially those with paranoid features to their illness. A psychiatrist is hard-pressed to assure a patient about confidentiality when there are headlines about databank breaches.

A pharmacist can legally contact a list of his or her pharmacy's patients, who have been prescribed certain drugs, in order to inform them about alternative drug therapies. A pharmaceutical company can pay the pharmacist to do this, though it cannot directly obtain patient information and contact patients. This allows pharmaceutical companies to indirectly promote targeted drugs to patients. Also, pharmacies can promote their own financial interests by urging a patient to use medications that are more profitable for the pharmacy. Marketing communications do not necessarily need to disclose these compensation arrangements.

APA believes that patients need to be certain that there will be no downstream release of information to marketers and that the security of their health records will be safeguarded. A strong CMS policy to that effect would give vendors a clear message of CMS' expectations, as this applies to e-prescribing systems and security. It is critically important that CMS respond to the e-prescribing security concerns of psychiatrists, as well as all physicians, and their patients.

As mentioned above, mental health records are particularly sensitive to release and disclosure, partly due to the unfortunate, pervasive social stigma about mental disorders. A patient might not want family, neighbors, or even a postal delivery person to see a postcard from a pharmacy suggesting that he or she is on psychotropic medication. Such communications could undermine mental health care, as patients avoid or delay it, to avoid stigmatization.

## CONCLUSION AND RECOMMENDATIONS

APA maintains that the goals and mission of effectuating widespread adoption of e-prescribing within the physician community will be fraught with barriers, unless CMS adopts a more judicious, cautious approach. Pilot testing of standards within their actual context of usage is imperative, along with a more realistic, workable effective date for e-prescribing compliance. What may constitute "adequate industry experience" with standards within one context, i.e., intra-entity transmissions or within partial e-prescribing systems, may well not work as anticipated within a different environment. For instance, problems may arise when psychiatrists, or, indeed, any physicians, in a small group practice use a fully integrated e-prescribing system to communicate with managed care companies and external pharmacies using different systems.

Only after evaluating the results of e-prescribing pilot projects using different systems across a spectrum of clinical settings, will it be feasible to determine precisely which standards, process areas or technologies require adjustment. All standards to be used for e-prescribing must have the capability of being used within products that work seamlessly across different data-interchange platforms and among all entities involved in the prescribing process. Moreover, the standards ultimately adopted as final foundation standards to be embedded within software, used via web portals and within e-prescribing systems hardware must be efficiently inter-functional and meet the intended practical and legal requirements. It will take some time to discover how to perfect these systems and CMS must not foreshorten this process, or it will prove to ultimately be at the expense of patients.

Psychiatric patients on prescription psychotropics are especially vulnerable to delays, glitches, and errors that could be caused by premature adoption of standards, resulting in ineffective systems. Since medication adherence is already a serious issue for such patients, even delays of a day or two in receiving prescription fills could seriously and adversely affect them. It will be much easier to collect data, provide feedback loops, and create corrective interventions within a smaller pilot-test system of e-prescribing, than within a large one. Moreover, fewer physicians and patients will be negatively affected when something goes awry within a pilot test, than within a wider context of usage. It simply makes practical sense to evaluate a major change of this dimension on the prescribing mechanisms for physicians on a small scale, before expanding the process into a larger patient-care environment.

Successes within the pilot tests can then be used to encourage further adoption of e-prescribing, while physicians remain confident that obstacles to effective use will be resolved at the pilot stage, before they adopt the technologies. In this way, e-prescribing will become a more palatable alternative to physicians, who will have a more definitive set of reasons to adopt it, with solid evidence of its advantages and confidence in its practicality. Physicians also require reassurance from CMS that policies will be adopted

that send a clear message to companies that commercial messages and design bias in software and hardware for e-prescribing will not be tolerated.

Pilot testing in 2006 will automatically advance the effective date for compliance, which has the added benefit of allowing sufficient time to promulgate the new Safe Harbor and new Stark II exception that give physicians the freedom to accept assistance in establishing e-prescribing systems. It will also be in line with the timeframe that will ensure physicians' access to federal grants to underwrite such systems. APA's specific recommendations are reiterated, below:

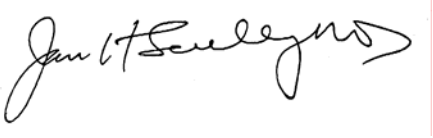
***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor for physicians to freely accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

***Recommendations-Pilot Testing:*** APA urges CMS to: 1) adopt the proposed standards as initial, rather than final, or use its discretion to pilot test these standards, despite their characterization as final, to determine their functionality and interoperability; 2) name other standards as initial ones; and 3) pilot-test all initial standards, preferably using several technological systems for comparative data, prior to deciding whether to adopt them as final foundation standards. For all the reasons and advantages articulated above, APA requests that CMS implement pilot testing for the proposed e-prescribing standards.

***Recommendation-Effective Date:*** APA believes that the effective date for e-prescribing rules should be moved to the end of 2007 for the following reasons: 1) to ease the burden of the Medicare Part D dual eligibles transition; 2) to provide time to issue NPIs, to allow physicians to obtain and implement grants; and 3) to allow time to finalize new laws protecting them from prosecution for accepting assistance with e-prescribing systems.

Thank you for your consideration of these comments.



James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

**Submitter :** **Ms. Ann Berkey** **Date: 04/05/2005**

**Organization :** **McKesson Corporation**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Attached please find McKesson Corporation's Comments on CMS-001-P.

CMS-0011-P-63-Attach-1.DOC

**McKesson Corporation**
One Post Street
San Francisco, CA 94104

**Ann Richardson Berkey**
Vice President
Public Affairs

April 5, 2005

The Honorable Mark McClellan
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8014
Baltimore, MD 21244-8014

**Attention: CMS-0011-P**

Dear Dr. McClellan:

On behalf of McKesson Corporation (hereinafter "McKesson"), we are pleased to provide our comments in response to the CMS proposed rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. As the world's largest healthcare information technology company, we are pleased to submit comments which reflect the unique breadth of our experience and expertise, our broad solution set and the range of our customers' perspectives on these important issues.

As a Fortune 16 corporation dedicated to providing information technology, care management services, automation, medical supplies and pharmaceutical products to virtually every segment of the healthcare industry, we understand the challenges as well as the opportunity for significant quality and efficiency improvements through the widespread adoption of e-prescribing. McKesson touches the lives of over 100 million patients in healthcare settings that include more than 5,000 hospitals, 150,000 physician practices, 10,000 extended care facilities, 700 home care agencies, and 25,000 retail pharmacies. With our technology solutions in 65% of U.S. health systems, McKesson is actively engaged in the transformation of healthcare from a system burdened by paper to one empowered by interoperable electronic solutions that improve patient safety, reduce cost and variability of care and improve healthcare efficiency. Our success in supply chain automation and electronic transaction processing and our experience in e-prescribing exemplify the benefits that can be derived from sustained efforts to improve stakeholder communication and to eliminate duplication of efforts in the healthcare delivery process.

McKesson has established a strong record of support and involvement in important federal and state health initiatives. We have been a pioneer in the introduction of drug savings cards to help lower the costs of pharmaceuticals through our administration of the

successful Together Rx™ card and our subsequent introduction of the CMS-endorsed Rx Savings Access™ Card. The Together Rx™ card has delivered over $600 million in savings since June 2002 to more than 1.5 million low-income seniors. McKesson's Rx Savings Access™ Card is providing Medicare beneficiaries with an average savings of 15-25% on the most commonly prescribed medicines and is accepted by over 95% of pharmacies nationwide. To date, more than 236,000 Medicare-eligible seniors are enrolled in this card and have realized over $62 million in savings on their prescription drugs.

McKesson has also taken a proactive approach to providing disease management programs for commercial, Medicaid and Medicare populations where we leverage our experience with patient services, pharmacy management and healthcare quality improvement activities. In nine states where we provide disease management services to Medicaid patients, we estimate those states are saving approximately two dollars for every dollar spent with McKesson, while improving both the health status of the patient population and physician satisfaction with the program. Late last year, we were awarded one of the Chronic Care Improvement Program (CCIP) demonstration projects by CMS for Medicare beneficiaries.

CMS has invited comments on proposed foundation standards for electronic or e-prescribing and on the impact of those standards on various stakeholders. We believe these standards have significant implications and benefits for all stakeholders, including physicians and other prescriber organizations, health plans, pharmacy benefit managers, retail pharmacies and other dispensing organizations, technology vendors, federal and state governments, and patients. Our comments not only respond to many of the questions raised in these proposed regulations; they also provide our recommendations in areas related to the broader implementation of electronic prescribing from both a technology and a business perspective.

## Section I Background

### A. Statutory Basis

McKesson recognizes that the proposed regulations are designed specifically for use in the Medicare Part D program; however, to ensure that there is only one set of industry standards for e-prescribing, we strongly encourage CMS to develop and support generally accepted standards that can also be utilized throughout the entire healthcare system, including for those not eligible for Part D benefits.

#### 1. Initial Standards versus Final Standards

We concur that there is adequate industry experience to proceed with initial implementation of these proposed standards without pilot testing. However, we would encourage formal monitoring of the process by CMS and ongoing evaluation of anticipated concerns as these standards are implemented. Specific areas of concern include:

- the use of proprietary standards that have not been placed into the public domain may create de facto monopolies;
- widespread deployment of e-prescribing transactions in the absence of a patient identifier may increase the risk of misdirected transactions;
- absence of a national standard for electronic signature may increase the cost of implementation;
- inefficiencies and additional costs may result from the absence of a pre-authorization standard;
- the use of NDC-11 codes to identify medications may cause delays in the ability to e-prescribe new medications or preparations; and
- the possibility that standards developed for the Medicare Part D program will not be extended to and scaled out for other populations, thus leading to the development of more than one industry standard for eligibility transactions.

While acknowledging these concerns, we continue to recommend that CMS deploy these foundation standards without pilot testing.

**2. State Preemption**

Currently, state regulations vary widely and could create significant barriers to entry and add unnecessary costs. Common state legal and regulatory hurdles that are encountered include:

- absence of or incomplete laws/regulations that authorize e-prescribing;
- requirements that e-prescribing be transmitted directly to a licensed pharmacy of the patient's choice, thereby limiting options for routing transactions;
- variability of "Dispense as Written" interpretations on a state by state basis;
- unclear and confusing electronic or digital signature requirements;
- requirements that e-prescribing entities be approved by State Boards of Pharmacy prior to implementation in the state; and
- DEA limitations and requirements for state controlled substance triplicate forms.

Since many medical "communities" extend beyond a single state's border, resolution of differences between state laws and federal policy will be required to speed the adoption and implementation of e-prescribing. To address that concern, McKesson supports federal preemption of state policies and standards that may be in conflict. Federal preemption of state e-prescribing laws will provide consistency between states. It will also promote adoption and reduce barriers to entry for prescribers, dispensers and vendors. The scope of the preemption outlined in the proposed rule promotes consistency relative to the foundation standards; however, the narrow scope still leaves room for continued variability from state to state in the adoption and regulation of e-prescribing.

**3. Anti-kickback Statute Safe Harbor and Stark Exception**

We strongly believe that the Stark safe harbor exceptions are critical to attain the provider adoption rates necessary to achieve the desired benefits of this e-prescribing initiative.

However, we believe that rapid and precise clarification of these exceptions is essential to ensure that provider organizations clearly understand and can utilize these exceptions to drive broad adoption.

**B. The NCVHS Process**

We have been favorably impressed with the effectiveness of the NCVVS process, and we strongly support ongoing use of this forum and process for obtaining industry expertise and guidance.

**C. Standards Design Criteria**

McKesson believes that the most significant factor in the rapid adoption of proposed standards by providers and information technology suppliers is ready, affordable access to all aspects of the standard necessary for its full implementation. Accordingly, key standards, including transaction standards (messages), data standards and identifiers (codes), and rules used for patient identification and patient matching, should be placed in the public domain and must not be the intellectual property of a single vendor. These standards may become the foundation of healthcare transactions, and once established, they will not be easily removed.

CMS should establish a clear policy that ensures any adopted standard is not burdened with intellectual property licenses that are royalty bearing or discriminatory. This royalty-free licensing policy should include the following elements:

1) disclosure of relevant existing or proposed patents by any participant recommending a standard; and

2) agreement by participants to license all essential claims to interoperability standards on a royalty-free, non-discriminatory and irrevocable basis. These measures will ensure that no one organization has the ability to exert undue control over the standards.

**F. Evolution and Implementation of an Electronic Prescription Drug Program**

McKesson supports the proposed criteria for determining foundation standards. It is critically important that foundation standards be developed through the consensus process used by ANSI-accredited Standards Development Organizations. Key industry stakeholders must recognize these as industry standards in order to ensure adoption and timely deployment throughout the industry. Upon designation of new or revised foundation standards, a compliance deadline of not less than two years from the designation date should be allowed for industry testing and deployment. Concurrent with the implementation of the initial standards, we recommend that pilot testing commence on other NCVHS recommendations that are not part of the foundation standards.

We also recommend that, for purposes of HIPAA compliance, e-prescribing should be considered within the categories of treatment, payment or operations when a determination is made as to the “minimum necessary information” required.

## G. Electronic Prescription Drug Program

We support NCVHS as the lead organization for review and recommendation of additional standards. We would also encourage NCVHS to organize forums and communicate with Standard Development Organizations to facilitate and expedite efficient and timely modifications to the initial standards. We support the use of an ANSI-accredited Standards Development Organization for the creation of new standards.

### Provider and Dispenser Identifiers

McKesson endorses comments from the Working Group on Electronic Data Interchange (WEDI) as noted below:

- NPI should be the primary identifier for prescribers and dispensers;
- current identifiers should be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access, are available;
- the required date for use of NPI in transactions in this proposed rule must not be sooner than the required date for use of NPI in HIPAA transactions. WEDI is concerned that there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before NPI can be mandated. The proposed date of January 2006 is unattainable because of non-availability of these NPI system capabilities. The NPI should not be required until the May 2007 deadline;
- legacy identifiers had capability for transaction routing that may not be provided by NPI or other data elements in standard transactions. This problem must be researched and solved. The solutions probably lie with adjustments to the data in the transactions, rather than adjustments to the NPI rules.

It is important to recognize that, irrespective of the value of the NPI for uniformly identifying healthcare providers, electronic prescribing requires that prescribers be additionally identified by an electronic "address" for the proper routing of transactions. Additionally, where the same prescriber operates out of more than one physical location, this routing information needs sufficient specificity to direct transactions to the correct prescriber location. The NPI alone cannot facilitate the routing of transactions. Accordingly, we recommend evaluation of alternatives for identification, including HCIdea, with the requirement that all standards be available in the public domain.

### Formulary and Medication History Standards

We support adoption of the RxHub file transfer protocol as the standard for medication history transmission and formulary transmission. As noted in our earlier comments, foundation standards, including codes and rules for patient identification, should be placed in the public domain. A pilot study should evaluate standards for communication of the "decision making process" (alerts and warnings received and over-ridden) from a prescriber to a dispenser.

Our support for RxNorm is reflected in the "Drug Information" section below; however, we want to emphasize its importance for formulary management as well.

**Drug Information**
In the absence of robust standards for identifying medications and therapeutic classes of medications, we support the use of the NDC-11 codes as a provisional medication identifier. We endorse the recommendations of the NCVHS advisory panel that the FDA accelerate and refine the process by which it creates, updates, and distributes the NDC-11 medication codes. We also recommend monitoring the effectiveness of the NDC-11 code as a means to identify dispensed medications.

We support evaluation of the RxNorm standard as a means to identify medications and therapeutic classes, and enable communication between prescribers, electronic health record systems, dispensing systems, vendors and the FDA. We recommend ongoing support for collaboration between the National Library of Medicine and the FDA.

**H. Summary of Status of Standards for an Electronic Prescription Drug Program**
McKesson supports efforts to establish these foundation standards rather than waiting until more comprehensive standards are accepted for patient medical histories and for electronic health records (EHRs). The adoption of foundation standards is a critical step in accelerating the broader adoption of e-prescribing and healthcare information technology. Long-term success will be contingent on the success of foundation standards, but will also be influenced by a multitude of other factors. Towards that end, we support the current activities of the Commission for the Certification of Healthcare Information Technology (CCHIT) relative to certifying EHR software and believe that the selection of these foundation standards will facilitate adoption of e-prescribing without compromising the EHR certification process. Furthermore, we encourage CMS to continue to explore additional means to minimize legal, regulatory and technical hurdles for prescribers and their solution providers, which will result in improved patient safety as well as lower costs.

**Section II Provisions of the Proposed Regulation**

**C. Proposed Requirements for Part D Plans**
We agree that internal standards need not be immediately revised to comply with these rules. In practice, we expect that internal standards will likely migrate to compliance with these rules as products are updated.

**E. Proposed Standards**

**1. Prescription**
McKesson concurs that prescription fill notification transactions be specifically excluded from the foundation standards until sufficient industry experience is determined, either through pilot program testing or by broad industry consensus on the business case for inclusion.

**2. Eligibility**
McKesson agrees with the proposed foundation standards that specify the NCPDP eligibility transaction standard for use by the pharmacies and the ASC X12N 270/271 eligibility standard for use by prescribers. The use of HL7 for e-prescribing eligibility verification should not be considered unless the matter is thoroughly reviewed and agreed upon by the various industry constituencies.

We concur with the proposal to use notice and comment rulemaking for substantive changes to the standards and to allow waiver of comments on minor modifications as long as "backward compatibility" with the previously adopted version is supported. However, the number of such minor modifications should be limited without requiring formal notice and comment. This would prevent a substantive change from "masquerading" as a series of minor changes. For substantive changes, we recommend a minimum of two years for implementation to ensure compliance by all industry participants.

**F. Compliance Date**
January 1, 2006 is a reasonable date for implementation of the foundation standards outlined in the proposed rule, provided that the transaction standards for formulary and medication history transactions are adopted by NCPDP and are accredited by ANSI.

**Section IV Regulatory Impact Analysis**

**A. Overall Impact**
While we support the establishment of foundation standards without waiting for more comprehensive medical history/EHR standards, increasingly hospitals and physicians are adopting integrated solutions that combine e-prescribing with other components of an EHR system. In fact, isolated e-prescribing applications in the ambulatory environment may not even exist by the time these standards are effective in 2009. To that end, we want to ensure that, if providers adopt an integrated EHR system, they will not lose the safe harbor provisions applied to e-prescribing that are noted in the Medicare Modernization Act.

We concur with CMS that the proportion of prescribers using e-prescribing will increase with the implementation of the Medicare Part D program; however, we believe widespread adoption could be rapidly achieved by removing two significant barriers. Exceptions to anti-kickback laws must be clearly defined and implemented prior to or concurrently with the proposed regulations on e-prescribing. Additionally, we encourage CMS to provide monetary incentives to encourage physicians to acquire and deploy e-prescribing technology.

**B. Impact on Health Plans/PBMs**
While many health plans automatically receive information from dispensing organizations via the telecommunications standard, they have limited or no experience

with the "front-end" transactions associated with formulary download and medication history. In fact, unless a health plan or PBM is part of RxHub, we are concerned that they may not have had the opportunity to appropriately test and gain adequate experience with the proposed standards in these areas. Furthermore, few health plans have actively participated in comprehensive e-prescribing programs like those in Massachusetts and Rhode Island and have little experience with the costs associated with supporting such programs, including labor and incentive costs for prescribers. While we concur with the potential benefit to payers and PBMs as outlined in the proposed rule, the cost impact may be larger than anticipated.

**C. Impact on Prescribers**

The potential benefits to prescribers from e-prescribing are well stated in the proposed rule. McKesson has successfully partnered with providers in Illinois and Iowa to achieve the following results:

- elimination of medical chart pulls related to medication questions or inquiries;
- 26% increase in nursing time spent with patients;
- 100% compliance with required prescription elements as compared to less than 60% compliance with paper prescriptions;
- reduced phone call volume related to formulary questions from pharmacies and pharmacy benefit managers;
- improved access to clinical information between care settings, especially the availability of information on outpatient medications in the hospital setting;
- 83% improvement in efficiency related to medication refills.

While early adopters have realized the benefits of e-prescribing, we believe that the adoption rates envisioned by CMS can be best achieved through a combination of economic incentives and exceptions from anti-kickback laws.

**D. Impact on Pharmacies and Other Dispensers**

The benefits outlined in the proposed rule are consistent with our customer experiences to date relative to e-prescribing and use of foundation standards for claims submission. However, dispensers may incur costs in training their staff to support inbound e-prescribing from area pharmacies. As area prescribers implement electronic systems, dispensers must work collaboratively with them to mitigate initial costs and ensure enhanced customer service, quick turnaround times, and greater patient safety.

E-prescribing provides pharmacies with opportunities to automate the medication process workflow. Pharmacists spend a significant amount of time on the telephone with refill and third-party payer issues. While patients can electronically request prescription refills from their pharmacy, pharmacies do not have similar processes for requesting pre-authorizations from physicians and third party payers.

Automating these processes will provide significant workflow benefits to pharmacies and other dispensers:

- saves time by automating the renewal/refill process and callbacks;
- provides the pharmacist more time for counseling;
- improves customer satisfaction and care: less waiting time and reduced potential for medication errors;
- provides more timely and effective response to medication recalls;
- provides more efficient formulary enforcement; and
- supports software integration with practice systems and a smooth workflow.

In addition to dispensing and distribution, a large part of the pharmacist's responsibilities is in the transcription, verification, translation, and communication of medication information. E-prescribing provides opportunities to enhance communications between physicians, nurses, pharmacists and patients by providing pharmacists with the ability to:

- monitor refill activity;
- monitor new written prescriptions filled;
- relay prescription fill and refill information to the prescribers; and
- monitor patient adherence to drug therapy.

**F. Impact on Others**

McKesson believes that all healthcare information technology vendors with ambulatory EHR products and all companies that currently offer or plan to offer e-prescribing applications will be impacted by the proposed rule. The cost of compliance with the provisions of the proposed rule for current e-prescribing vendors will vary based upon their current compliance with proposed standards. Future entrants to the marketplace should benefit from the adoption of clearly defined standards. As a vendor with established e-prescribing products, we believe that our own cost of compliance with the proposed regulations will not be excessive, as long as the proposed standards do not add additional royalty requirements or intellectual property barriers to our current implementation.

**Conclusion**

In conclusion, we would like to reiterate our support for the following:

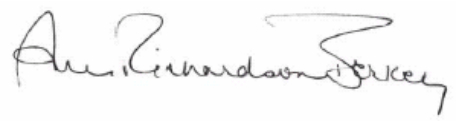
- implementation of the proposed foundation standards for e-prescribing without pilot testing;
- a requirement that standards not be proprietary or encumbered by intellectual property claims;
- federal preemption of state e-prescribing policies and regulations; and
- exceptions from Stark and other anti-kickback laws to expedite adoption of e-prescribing.

As a major healthcare supply management and information technology company, McKesson appreciates the opportunity to share its views on the proposed regulations to

adopt standards for an electronic prescription drug program under the Medicare Modernization Act. These initial regulations are critical and we applaud the agency's efforts to undertake this important first step. We look forward to working with CMS and the Administration as you implement this final rule and as you address other important issues that must be resolved to ensure widespread adoption of e-prescribing.

Please do not hesitate to contact me with any questions. I can be reached at (415) 983-8494 or ann.berkey@mckesson.com.

Sincerely,



Ann Richardson Berkey
Vice President, Public Affairs

**Submitter :** **Ms. Lisa Geiger** **Date: 04/05/2005**

**Organization :** **American Health Quality Association**

**Category :** **Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see the attached comments from the American Health Quality Association.

CMS-0011-P-64-Attach-1.DOC

THE AMERICAN HEALTH QUALITY ASSOCIATION

1155 21st Street, NW
Suite 202
Washington, DC 20036
T 202.331.5790 • F 202.331.9334
www.ahqa.org

April 5, 2005

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore MD 21244-1850

Re: file code CMS-0011-P

Via e-mail

To Whom It May Concern:

The American Health Quality Association (AHQA) is a national nonprofit membership association dedicated to improving the safety and effectiveness of health care. AHQA represents the national network of Quality Improvement Organizations (QIOs) that work with hospitals, medical practices, health plans, long-term care facilities, home health agencies, consumers and employers to encourage the spread of best clinical practices and improve systems of health care delivery. Section 109 of the Medicare Modernization Act of 2003 (MMA) specifically instructs the QIOs to work with Medicare Advantage plans, standalone prescription drug plan sponsors and fallback plans, as well as providers and practitioners, on quality improvement initiatives that are intended to improve prescribing and medication use for those beneficiaries enrolled in Medicare Part D.

E-prescribing is an important tool for health care providers to learn about, adopt and implement in their practices in order to achieve improvements in prescribing and medication use. The Medicare QIOs have been tasked by CMS in the next Statement of Work (SOW) to provide assistance to physician offices and pharmacies to promote the adoption and effective use of health information technology including e-prescribing. AHQA is pleased to comment on the proposed rule providing for initial uniform electronic prescribing standards.

AHQA supports the approach CMS has taken in the development of uniform e-prescribing standards, in particular, the Agency's accelerated process for adoption of standards. Further, AHQA supports CMS' decision to require Part D plans to both comply with and support initial standards by the start of the Part D benefit on January 1, 2006, thereby encouraging early adoption of e-prescribing.

The QIO community is uniquely positioned to assist the Agency with encouraging physicians to invest in health information technology, including e-prescribing, to support CMS' goals of improving health care quality and patient safety. Beginning in August, QIOs will work with providers on the adoption and implementation of e-prescribing as part of the next SOW. AHQA submits the following recommendations for CMS's consideration as the Agency continues with the development and adoption of additional standards:

- CMS identified several additional standards to be developed, including provider and dispenser identifiers, formulary and medication history, drug information, and medical history. It will be important for the QIOs to have access to the data collected via e-prescribing in order to conduct the tasks required of the QIOs under the 8th SOW. For instance, under medical history, the data should be made available to the QIO and should include all data elements necessary for QIOs to work on the Doctor's Office Quality (DOQ) measures using this data. Access to this data will also be necessary for the QIO work in the 8th SOW that focuses on improving prescribing and medication use in the Part D benefit. In particular, QIOs will be asked to work on quality improvement activities related to decreasing drug-drug interactions, generic prescribing ratios, and medication therapy management programs. Data related to these and other topics which are accessible via e-prescribing must be made available to the QIOs.

- As noted in the preamble to the proposed rule, the MMA authorizes grants to doctors to help them purchase computers, software, and training necessary for e-prescribing. The grants may be targeted to rural physicians and those with a large share of Medicare patients. As community-based organizations with strong local relationships with physicians in the state, QIOs are a logical place for CMS to look to for assistance with identifying physicians who would be good candidates for these grants. Once grants are awarded, QIOs can work closely with those physicians to ensure they use their e-prescribing systems to their fullest capability.

- CMS estimates that between 5 and 18 percent of prescribers are conducting e-prescribing today and approximates that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years. QIOs are in a strong position to identify physician practices ready to move forward with e-prescribing. In this way, QIOs will be a valuable partner with CMS to encourage the wide-spread adoption of e-prescribing as a component of an overall electronic health record. Incentivizing QIO efforts on e-prescribing may help CMS achieve the gains in the number of prescribers using e-prescribing envisioned in the proposed rule.

- QIOs can be an invaluable partner with CMS in driving widespread adoption of e-prescribing. However, to achieve this potential, stronger incentives must be in place to encourage QIOs do so. As currently written, the 8th SOW does not include strong incentives for QIOs to focus on the promotion of e-prescribing among large numbers of physician offices. Focusing heavily on e-prescribing alone does not benefit the QIOs in their contractual performance evaluation. Giving QIOs more credit in the 8th SOW for dramatically increasing e-prescribing adoption rates among a larger number of physician practices could generate a series of immediate quality and safety gains. AHQA

encourages CMS to incentivize QIOs to heavily promote and support the adoption of e-prescribing.

- CMS invited public comment on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing. AHQA encourages CMS to provide guidance as necessary to drive adoption of e-prescribing, including financial incentives and support for physicians and other prescribers who choose to utilize e-prescribing.

- CMS requested information on the costs or benefits for a given type or size of provider to conduct a cost-benefit analysis for that provider type or size. AHQA recommends that CMS ask selected QIOs to work closely with providers in their state to study this. QIOs have "on-the-ground" physician contacts that can easily facilitate this type of analysis and provide a direct feedback mechanism between physicians and CMS.

AHQA is excited by the potential that e-prescribing has to improve patient safety and quality in the delivery of health care. AHQA and the QIOs stand ready to assist CMS with promoting the benefits of e-prescribing to prescribers and pharmacies. If we can be of any assistance to CMS please contact Lisa Geiger of my staff at lgeiger@ahqa.org or by phone at (202) 261-7577. Thank you for your consideration of our comments.

Sincerely,

David G. Schulke
Executive Vice President

**Submitter :** **Mrs. Diana Dennett** **Date: 04/05/2005**

**Organization :** **America's Health Insurance Plans**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-65-Attach-1.DOC

**America's Health Insurance Plans**

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org


April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

## Application of Standards Within Organizations

***Issue:*** The standards should not be applied to electronic prescribing communications within a "closed network."

***Discussion:*** The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan…." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity are not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

***Recommendation:*** AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS either reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103) or adopt the following language:

*A "closed enterprise" is:*

*1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider that share a common electronic health information system;*
*2. An organized system of health care in which more than one covered entity (as defined by HIPAA) participates and in which the participating covered entities:*
- *a. Hold themselves out to the public as participating in a joint arrangement; and*
- *b. Participate in joint activities that include at least one of the following:*
  - *i. Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; or*
  - *ii. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; and*
- *c. Share a common electronic health information system.*

## Pilot Testing

***Issue:*** Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

***Discussion:*** The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations, varying transaction volumes and system capabilities, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

***Recommendation:*** AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

## Standards for Formulary Representation and Medication History

***Issue:*** The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

***Discussion:*** The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the

[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).

RxHub protocol as a basis for these standards. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA approved standards development organization.

NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history. Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested and implemented.

***Recommendation:*** AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

**Process for Modifying the Standards**

***Issue:*** The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

***Discussion:*** The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, CMS should consider the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to CMS which should release them as an interim final rule with a 60 day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted and implemented to allow any necessary changes to technology and business systems.

***Recommendation:*** AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

**The National Provider Identifier**

***Issue:*** Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

***Discussion:*** The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

***Recommendation:*** AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.

**State Law Preemption**

***Issue:*** The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

***Discussion:*** The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

***Recommendation:*** AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

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[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

**Submitter :** **Date: 04/05/2005**

**Organization :** **American Academy of Pediatrics**

**Category :** **Other Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-66-Attach-1.DOC

American Academy of Pediatrics

**STATEMENT**

**FROM THE AMERICAN ACADEMY OF PEDIATRICS**

**IN RESPONSE TO THE**
**CENTERS FOR MEDICARE AND MEDICAID SERVICES MEDICARE PROGRAM**

# E-PRESCRIBING AND THE PRESCRIPTION DRUG PROGRAM PROPOSED RULE

**APRIL 5, 2005**

American Academy of Pediatrics
141 Northwest Point Boulevard
Elk Grove Village, IL 60007-1098
847/434-4000 (Phone)
847/434-8000 (Fax)

## Introduction

This response is submitted on behalf of the American Academy of Pediatrics (AAP), an organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and surgical specialists who are dedicated to the health, safety, and well being of infants, children, adolescents, and young adults.

The AAP and its members have long been committed to improving the health care system to provide the best and safest health care for infants, children, adolescents, and young adults. This commitment includes advocating for the design of health care systems to prevent errors. If designed with particular pediatric needs in mind, E-prescribing has demonstrated the ability to improve safety, efficacy, and efficiency in children's health care.

## CMS-0011-P BACKGROUND

With regard to State Preemption of the Proposed Rule, the American Academy of Pediatrics believes that the Federal standard for electronic prescribing should preempt state regulations prohibiting such transactions, particularly as they relate to controlled substance prescribing and digital signatures. Many states currently have their own requirements, including the use of special paper forms, for the prescription of controlled substances. As noted in the Proposed Rule (IMPACT ANALYSIS, Impact on Prescribers), prescribers spend a significant amount of time responding to requests for refills. In pediatrics, controlled substances are routinely prescribed as therapy for Attention Deficient Hyperactivity Disorder (ADHD) and related conditions. Such prescriptions require frequent provider approval of refill requests. State regulations requiring such prescriptions to be handled on paper limit the potential for error reduction through new technologies, such as e-prescribing. Similarly, states have proscribed multiple standards for signatures on controlled substance prescriptions, both in paper and electronic form. Multiple standards for signatures are a significant roadblock to broader adoption of e-prescribing.

## CMS-0011-P PROVISIONS

The American Academy of Pediatrics supports the Proposed Rule as a floor on e-prescribing functionality, above which many e-prescribing software vendors will provide additional functionality. As such, the proposed Standards are reasonable; however, the American Academy of Pediatrics would encourage the adoption of an additional functional standard related to interaction checking. Where drug-drug or drug-allergy interaction checking has been completed and overrides of resulting alerts have been allowed before transmission to the dispenser, a flag should be incorporated into the information to be transmitted to alert the dispenser that the potential interaction was recognized and overridden. This would further reduce the need for follow-up communications between the prescriber and dispenser. Such an event might occur where the pharmacy's record indicates a patient allergy to a particular medicine when the prescriber has determined the allergy is insignificant or erroneous.

In addition, the Rule seeks to establish the National Provider Identifier (NPI), an upcoming HIPAA standard, as the standard identifier for prescribers and dispensers, but it does not address a standard identifier for patients. The American Academy of Pediatrics believes that a uniform National Patient Identifier is necessary to allow interoperability in e-prescribing, electronic health records, and other health information technology applications. We would encourage the creation of a unique National Patient Identifier, as originally specified under HIPAA. This is particularly important for pediatrics, in which patients frequently present with no name (in the case of a newborn) or with changing names (which may or may not match that of the parents). The American Academy of Pediatrics recognizes the controversy surrounding the issue of a National Patient Identifier and recommends that use of such an identifier be restricted to communications covered by the HIPAA Privacy Rule.

Finally, the American Academy of Pediatrics believes that the new prescription transaction standard should include the following:

1. In addition to the patient's name, residential address, and birthdate, basic demographic information for pediatric prescribing should include the names and phone numbers (voice, cell) for both parents, the custodial parent, or other guardians, if appropriate. The parent's name may be different than the patient's name, and prescriptions might be filled by either of two separated parents from different addresses.

2. Standardized transmission of patient weight and weight units, the date on which the weight was obtained, should be included on the prescription. Systems should be able to calculate patient age from birthdate.

3. Diagnosis should be included (optionally) on the prescription or as part of the transmission, as it is required in some states for controlled substances, e.g. Attention Deficit Hyperactivity Disorder for prescriptions of methylphenidate.

4. The ability for dosages to be printed in fractions of dosage forms should be standard.

5. An optional note field is needed for the prescriber to communicate to the pharmacist any other special information or request. This note should print on the prescription or transmit electronically.

**CMS-0011-P IMPACT ANALYSIS**

Costs to implement e-prescribing may be much greater than estimated. Many providers do not have the office infrastructure to support e-prescribing. Costs to install computers, wireless routers (particularly for those in rural areas who may not have access to cable or DSL Internet connections), to set up networks, and to purchase personal digital assistants (PDAs) could incur costs above $2,000^{*}$ per prescriber. For prescribers who are already using some technology in their practices, interfaces to practice management or electronic health record software, preferred formularies, and decision support, purchase of PDAs and wireless routers, etc., would also have additional start-up costs. Overhead costs may be in the range of 15-20% annually. Finally, the

impact on workflow efficiency of a different, unconnected system must be considered. This is particularly true for smaller practices that cannot afford an EMR system that contains e-prescribing.

It is also necessary to point out that financial incentives to providers through Medicare programs do not benefit most pediatricians. Incentive programs focusing solely on Medicare could therefore put pediatricians and other child health care providers at a disadvantage and restrict the quality improvement benefits of e-prescribing to the adult population. The American Academy of Pediatrics therefore recommends that any financial incentives approved for prescribers through the Medicare program also be extended equally to prescribers participating in Medicaid programs.

**CMS-0011-P ADDITIONAL COMMENTS**

Finally, the AAP urges that practicing pediatricians be involved in the development of further e-prescribing standards. It is often the case that pediatricians have to modify standards and recommendations designed for adults when their patients have not been taken into consideration during the design and testing stage of health care technology, including E-prescribing systems. For example, the age and weight of a child can make a medically significant difference in selecting an appropriate dose. Specific medications may be contraindicated for particular diagnoses or for particular age groups. Awareness of these and other issues in the design stage of E-prescribing systems can help to reduce the error rate in prescribing medications for children. Because prescribing for a pediatric patient can be more complex than prescribing for an adult, it is important that the special pediatric considerations be factored in during the development of standards, not as an afterthought.

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[*] Calculation based on the following: $500 – computer; $30/month ($360 for first year) for high-speed Internet access; $50 – wireless router; $150 – installation of computer, router, and security; $400 – PDA; $500 – e-prescribing software (including pharmacy database, formularies, decision support); $200 – printer.

**Submitter :** **Mr. Ken Whittemore Jr,** **Date: 04/05/2005**

**Organization :** **SureScripts**

**Category :** **Health Care Industry**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attached

CMS-0011-P-67-Attach-1.DOC

CMS-0011-P-67-Attach-2.DOC

April 5, 2005

Submitted electronically via
http://www.cms.hhs.gov/regulations/ecomments

The Honorable Mark B. McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014, Baltimore, MD 21244-8014

**RE: CMS-0011-P; Medicare Program; E-Prescribing and the Prescription Drug Program; 42 CFR, Part 423**

Dear Dr. McClellan:

This letter is in response to the proposed rule that the Centers for Medicare and Medicaid Services (CMS) published in the Federal Register, Volume 70, Number 23, beginning on page 6256 on February 4, 2005. SureScripts appreciates the opportunity to comment on these proposed rules that call for the adoption of foundation standards that will support the implementation of an electronic prescription program designed to improve the overall prescribing process for millions of Medicare beneficiaries. SureScripts has testified before, and offered additional advice and assistance to, the National Committee on Vital and Health Statistics Subcommittee on Standards and Security as it gathered input throughout 2004 on electronic prescribing standards that might be used for the electronic prescribing program for Medicare. We look forward to continuing to work with CMS to implement these foundation standards and the proposed rules in a manner that improves the safety, efficiency, and quality of the overall prescribing process for all essential stakeholders.

## Introduction

SureScripts was founded in August of 2001 by the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA), which together represent the interests of the 55,000 chain and independent pharmacies throughout the United States. The company is committed to building relationships within the healthcare community and working collaboratively with key industry stakeholders and organizations to improve the safety, efficiency and quality of healthcare by improving the overall prescribing process. At the core of this improvement effort is SureScripts Messenger™ Services, a healthcare infrastructure

that establishes electronic communications between pharmacists and physicians and enables the two-way electronic exchange of prescription information. You and your staff can find more information about SureScripts at www.surescripts.com.

SureScripts Comments Regarding the Prohibition of Inappropriate Messaging in Electronic Prescribing Systems and Transactions

Noticeably absent from this proposed rule is any language that effectuates the requirement in the MMA that prohibits the intrusion of inappropriate messaging into the electronic prescribing process at the point of care (defined as both the physician office and the pharmacy). Specifically, the MMA states that the electronic prescribing standards that the Secretary adopts shall "*allow for the messaging of information only if it relates to the appropriate prescribing of drugs, including quality assurance measures and systems to reduce medication errors, to avoid adverse drug interactions, and to improve medication use*." Congress was quite clear in stating in the MMA that inappropriate messaging at the point of care during the prescribing and dispensing processes must not be allowed in the Medicare electronic prescribing program.

SureScripts is acutely aware of the strong desire and intent that some entities, including but not limited to technology vendors, manufacturers, payers, pharmacy benefit managers (PBMs), pharmacies, laboratory service providers, and others in the clinical technology space have to inappropriately influence physicians' choice of medication therapy and patient's choice of pharmacy for Medicare beneficiaries. Inappropriate and misleading messages could be and, in some cases, are planned to be delivered with the intent to influence a physician's choice of therapy and/or a patient's choice of pharmacy by entities who financially or strategically gain from the message delivery, physician's decision of therapy, or patient's choice of pharmacy. Some plans are to (1) disguise this message as a "clinical alert" based upon biased research not published in the public domain nor sourced at the time of message delivery or (2) the alert would be positioned as saving a patient money when further investigation would prove the selection of pharmacy in fact costs the patient additional moneys in out-of-pocket costs. There is little question that these and other entities will engage in this inappropriate messaging unless CMS creates clear, specific, and unequivocal rules prohibiting such activities within the practice of electronic prescribing for the Medicare prescription drug program as provided for in the MMA.

SureScripts emphatically urges CMS to incorporate into its final MMA rule on electronic prescribing strong and specific prohibitions against the types of inappropriate messaging that are discussed in this response. Sample rules related to inappropriate messaging are attached hereto as possible model language for consideration by CMS. These guidelines have been developed and modified over the last two to three years by SureScripts, and have been agreed to by many technology vendors and multiple other stakeholders including health systems, pharmacies, physician groups, pharmaceutical manufacturers, and payers. We believe these messaging guidelines could serve as the foundation of policies related to inappropriate messaging. Doing any less will permit an environment of abuses to evolve that will surely impede the rapid

adoption of electronic prescribing and electronic health records that was contemplated by Congress as it created the MMA.

SureScripts Responses to CMS Requests for Comment on the Proposed Rule

(We have arranged our comments to follow the captions and overall organization of your requests for comments, which is consistent with the format requested in your notice of proposed rulemaking.)

BACKGROUND

A. Statutory Basis

*CMS: Electronic media is defined under HIPAA to include both electronic storage media and transmission media, including the ``internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media." (45 CFR 160.103). However, given the development of new technologies, we invite public comment on applying this definition to determine when prescribers and dispensers are electronically transmitting prescription and certain other information, and therefore, should be required to comply with the e-prescribing standards.*

**SureScripts Comments:** We agree that all of the electronic media described above can and often are used to transmit prescriptions electronically, which does make this definition useful in determining when prescribers and dispensers are electronically transmitting prescription and certain other information. To these media we would add secure wireless communication technologies, which are also used to transmit electronic prescriptions, especially when PDA and other handheld devices are employed by prescribers.

*CMS: Finally, we believe that we have met the statutory requirement for industry consultation because we actively participated in the NCVHS process, and we requested and received industry comments on adequate industry experience with existing standards through the Medicare Prescription Drug Benefit proposed rule. We are also requesting comments in this proposed rule. The need for pilot testing of future standards will be determined when additional standards are recommended.*

**SureScripts Comments:** SureScripts testified orally and in writing to NCVHS on a number of topics related to electronic prescribing throughout 2004 and into 2005. Our experience during this time was that both NCVHS and CMS personnel were keenly interested in learning about electronic prescribing standards that are being used effectively by the industry and with which of those standards the industry might already have adequate experience. Thus, we agree that CMS has met the statutory requirement for industry consultation as required by the MMA.

*CMS: Federal Preemption of State Laws—We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

**SureScripts Comments:** SureScripts has had extensive experience with the adverse impact that state pharmacy laws and regulations and other local rules can have on the implementation of electronic prescribing, which is why we favor of a broad preemption of state rules that interfere with the adoption, implementation and/or operation of electronic prescribing standards or the elements of the electronic prescribing infrastructure.

SureScripts recognized from the start that the manner of issuance of prescriptions was governed by state board of pharmacy rules. The knowledge that these rules would apply to the creation and transmission of electronic prescriptions prompted us to make an across-the-board review of these rules throughout the states in 2002. This review indicated that electronic prescribing connectivity was, at least in theory, permissible in most states.

Over time, however, as SureScripts began planning in earnest to move forward with electronic prescribing in specific states, it became clear that additional regulatory due diligence was needed. It was not sufficient to know if electronic prescribing was permitted in theory, rather, experience taught us that the critical and truly pertinent question was: "Do the laws and regulations in a particular state permit electronic prescribing *the way in which SureScripts planned to implement it*?" Answering this question has not been easy, as it has involved a time-consuming process of researching and analyzing specific, in-depth technology and procedural issues, and it is a process that is still not complete even three years later.

Through this ongoing process, SureScripts has encountered a number of common state legal and regulatory hurdles, which include:

- An absence of laws and regulations that authorize electronic prescribing connectivity
- **Incomplete laws and regulations enabling electronic prescribing connectivity***
- **Laws and regulations that were created early on and thus don't "fit" the technology***
- **Highly specific dispense-as-written requirements that cannot be met using electronic technologies***
- **Unclear electronic or digital signature requirements***
- Requirements that electronic prescribing connectivity entities and prescribing technology vendors including stand alone prescribing applications and electronic health record solutions be approved by the board of pharmacy prior to implementation in the state

- **Extraneous laws and regulations that have been interpreted as applying to electronic prescribing connectivity***

SureScripts' Regulatory Affairs staff has successfully developed specific tactics for overcoming most of these hurdles and, where they remain, is working closely with the boards of pharmacy in those states to overcome them.

Of all of the state hurdles, though, the specific one that has proven to be most troublesome and widespread is language to the effect that:

> *All Prescription Drug Orders communicated by way of Electronic Transmission shall be transmitted directly to a Pharmacist or Certified Pharmacy Technician in a licensed Pharmacy of the patient's choice* ***with no intervening Person having access to the Prescription Drug Order*;***

This language is taken directly from the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act, and it has been adopted in various forms by most of the states. We have found time and time again that the underscored language above presents a barrier to the implementation of electronic prescribing in the states. Sometimes these barriers are a result of how this exact language is interpreted by state regulatory agencies, and other times it is the result of a particular state having embellished upon this language, thereby making it totally unworkable. While we understand that the intent of this language is to protect patient confidentiality and guarantee that electronic prescriptions are not altered during the transmission process, the effect of this broad language and the way that it has been interpreted in many states has been to prohibit the use of standard telecommunication protocols to implement the technology. These many variations and interpretations of this one small portion of the model act language clearly argue in favor of a broad preemption to this type of language.

With regard to CMS's specific questions regarding preemption, SureScripts believes that the examples listed above that are bolded and denoted with an asterisk should be preempted in order to enable electronic prescribing to move forward nationwide. However, following CMS's logic that there would have to be a Federal standard adopted through rulemaking that creates a conflict for a State law to be preempted, it is hard to envision that any of them would be. For example, in what ways would the foundation standards recommended within this proposed rule conflict with any of the state rules summarized above? We at SureScripts are at a loss to think of any. In other words, if the MMA preemption provision cannot be used to eliminate any of the actual obstacles to the implementation of electronic prescribing listed above, then of what use to CMS or the industry is the MMA preemption provision? In order to be truly useful, the MMA preemption provision will have to preempt not just those state rules that conflict with electronic prescribing standards, but also those state rules that interfere with the actual operation of various components of the electronic prescribing infrastructure.

As to the breadth and depth of the MMA preemption provision, SureScripts believes that said preemptions must apply to the broadest set of transactions and entities. Only applying preemption to the

electronic prescribing program under Part D will create a bifurcated set of rules that will be difficult for providers to understand and follow. The boards of pharmacy realized ten years ago that this would be the case with the OBRA '90 rule, and therefore decided that the patient counseling and recordkeeping requirements of that Federal rule should apply to all patients. Hence, it is entirely appropriate and logical that CMS should acknowledge the problems inherent in a two-tiered electronic prescribing program and avoid said problems by applying the MMA preemption provision as widely as possible.

Lastly, though we at SureScripts (as well as others in the industry, we suspect) are coming close to the point where we have successfully navigated around the state regulatory obstacles to electronic prescribing in all states, such rules do change. Technology also changes and evolves over time. Both of these facts argue toward a broad MMA preemption, because electronic prescribing should not be subject to the shifting and variable influence of regulations. Innovation in the field should be supported, not stifled, by regulations, and only a broad MMA preemption can guarantee this.

D. Current Prescribing Environment

*CMS: Today, physicians and other health care providers make their drug-prescribing decisions using whatever medical, medication, and eligibility information that is known or available to them. Then they give a handwritten prescription to the patient or fax it to the patient's pharmacy of choice. At the pharmacy, tasks are somewhat more automated. Through electronic claims, eligibility, and benefits submission, the dispensing pharmacist may learn about drug interactions, disease management concerns, the need for prior authorization, or lower cost alternatives. The pharmacist may then contact the prescriber by phone for approval of changes, refills, or renewals. This process can be very repetitive and time consuming for both the pharmacist's and the prescriber's office staff. According to some estimates, almost 30 percent of prescriptions require pharmacy call backs, resulting in 900 million prescription-related telephone calls that are placed annually.*

**SureScripts Comments:** We encourage CMS to modify the *Current Prescribing Environment* section so that it also reflects the fact that community pharmacists gather and make use of significant patient clinical and medication information during the course of their practices. It is critical that local, regional, and national health information networks understand the value of including community pharmacies in their electronic information sharing networks as the national health care information technology network is built out.

In particular, Congress recognized that community pharmacists have a vital role in enhancing therapeutic outcomes and reducing medication errors and adverse drug interactions when it enacted the Omnibus Budget Reconciliation Act of 1990. While OBRA '90 applies only to Medicaid recipients, it was not long before all the state boards of pharmacy passed laws and/or regulations that assured that this higher standard of pharmacist care for Medicaid patients would be available for all of their citizens.

OBRA ’90, and the state pharmacy practice rules that expanded OBRA ‘90’s coverage to all state citizens, requires a set of prospective drug utilization review activities that are more extensive than those required by the MMA. In addition is the point that OBRA ’90 also required that:

> “A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:
> “(aa) Name, address, telephone number, date of birth (or age) and gender.
> “(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.
> “(cc) Pharmacist comments relevant to the individual’s drug therapy.”

The OBRA ’90 required maintenance of patients’ diseases, allergies, drug reactions, list of medications and relevant devices, will certainly need to be included with in patients’ electronic medical records (EMRs) in addition to other electronic prescribing information required by the MMA in order for said records to deliver their full clinical value. Therefore, SureScripts strongly recommends that CMS acknowledge this fact in the *Current Prescribing Environment* section of this proposed rule.

F. Evolution and Implementation of an Electronic Prescription Drug Program

*CMS: We propose to use the following criteria to assess adequate industry experience, based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:*

*The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

*The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

*The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

**SureScripts Comments:** As is mentioned above, SureScripts did provide testimony to NCVHS during its 2004-2005 hearings, and we specifically spoke to the issue as to which industry standards have been used to date to implement electronic prescribing on a nationwide basis. We believe we have an excellent intuitive understanding of which electronic prescribing standards have “adequate industry experience,” and thus should not need to be piloted in 2006. We realize, however, that it is appropriate for CMS to formalize a definition of “adequate industry

experience" in order to give the industry an accurate yardstick with which to judge various standards. The solution at which CMS has arrived in offering these three criteria is useful, understandable, reasonable and elegant, and the use of these criteria yields an accurate, real-world assessment of the standing of standards in question. As such, the only qualifiers that we would add to these three criteria would be that:

(1) The first criteria should actually focus on the ANSI-accreditation status of the *standards development organization (SDO)* rather than the standard itself. In other words, the NCPDP SCRIPT Standard should be adopted as an MMA foundation standard because it was created by NCPDP, which is an ANSI-accredited body. We make this recommendation because we are concerned that in some cases, waiting until a *standard* itself has worked its way through the ANSI-accreditation process may well cause an unnecessary delay of months or even years before its adoption.

(2) We suggest expanding the scope of the second criteria so that it requires broad use by multiple different types of industry participants, such as pharmacies, prescribers, PBMs, payers, etc. Our reasoning here is that a standard must have widespread utility in order to be designated as an MMA foundation standard. High transaction volumes among a small number of like users should not satisfy this criterion.

If CMS takes these qualifiers into consideration, SureScripts will agree that the use of these three criteria is appropriate when seeking to determine if a standard does, in fact, have adequate industry experience, and we will support their use wholeheartedly.

*CMS: In its September 2, 2004 letter to the Secretary, the NCVHS recommended that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future. We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

**SureScripts Comments:** We recommend that HHS adopt minimal version levels of foundation and final standards, that HHS depend on existing SDO enhancement processes for newer versions, and that health care organizations be permitted to use newer versions without delay provided there is backward compatibility. We further recommend that NCVHS hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS should recommend such changes to HHS in much the same way as it has made its MMA electronic prescribing standards recommendations thus far. If NCVHS considers said changes to be substantive, we suggest that HHS issue an NPRM within 90 days. If the change is not substantive, we suggest that notice and comment be waived.

G. Electronic Prescription Drug Program

*CMS: Provider and Dispenser Identifiers. The MMA does not expressly direct the Secretary to require the use of unique identifiers for prescribers and dispensers in e-prescribing transactions. However, the NCVHS found that it was important to address the issue of provider identifiers for various e-prescribing standards it reviewed and, more generally, for an electronic prescription drug program. We agree. After assessing a number of candidate identifiers, the NCVHS further recommended the use of the National Provider Identifier (NPI) as the primary identifier for dispensers and prescribers, once it becomes available.*

*HHS is considering requiring the use of the NPI as the provider identifier for an electronic prescription program under Medicare Part D. We believe that it is necessary to have a unique identifier for these transactions. The NPI is the preferred option, because it is a standard that many entities will be required to use under HIPAA. If use of the NPI is required for e-prescribing transactions involving Medicare Part D drugs at the time the benefit is available in January 2006, prescribers, pharmacies, pharmacists, Part D sponsors and potentially other entities would be required to implement the NPI for e-prescribing transactions earlier than the current compliance date for the HIPAA covered transactions.*

*The NCVHS also urged HHS to accelerate the enumeration of all providers to support transition to the NPI for e-prescribing. We have been planning to enumerate HIPAA covered providers over the course of several years.*

*Accelerated NPI usage for e-prescribing, therefore, may not be possible, as HHS may not have the capacity to issue NPIs to all covered providers by January 1, 2006. Furthermore, there is a possibility that unforeseen system or budget concerns could delay provider enumeration, and, therefore, the date by which the NPI would be available for use in e-prescribing under Medicare Part D. We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

**SureScripts Comments:** A prerequisite to the suggestion that the NPI be used as an identifier for Medicare Part D e-prescribing transactions is the absolute requirement that the NPI fully meet the needs of participants in the electronic prescribing industry. The two primary and essential functions that a provider identifier must fulfill in electronic prescribing transactions are to: (1) identify who the provider is and (2) tell how the message must be routed in order to reach the provider. There is no question that, by definition, the NPI will satisfy the first requirement, but it is our understanding that, as currently configured and being implemented, the NPI will not satisfy the second requirement. Having the first functionality without the second renders the NPI no more useful that other potential identifiers, and less useful than others currently in use. This functionality deficit of the NPI will require industry participants to create significant work arounds, which should not be the case and which means the NPI is a less-than-ideal choice of

identifier for electronic prescribing transactions. This clearly argues against requiring the use of the NPI for the electronic prescription program under Medicare Part D.

If on the other hand, CMS was to see to it that the NPI was changed to include routing information, it would make the NPI an excellent choice of a provider identifier for Medicare Part-D and other e-prescribing transactions. As we testified last year to NCVHS, the absence of a fully functional prescriber ID in the marketplace led SureScripts to create its own SureScripts Provider ID, or SPI. This has been an expensive, time-consuming endeavor, and it would not have been necessary if a product existed in the marketplace that met both of the primary requirements for an electronic prescribing ID discussed above. Therefore, we encourage CMS to make the changes necessary in order for the NPI to serve as a fully functional electronic prescribing identifier. If this is done, SureScripts will embrace, adopt and support the NPI.

Finally, should the NPI be transformed into a fully functional identifier that is completely useful to the electronic prescribing industry, its use should not be required sooner than the date for use of the NPI in HIPAA transactions, and there must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before the NPI is mandated. In the interim, participants in the electronic prescribing industry should be allowed to continue to use whatever provider ID system(s) that they have been using, which in SureScripts' case would be our SPI. SureScripts would be opposed to CMS requiring the use of any other provider ID system during the interim.

*CMS: NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

**SureScripts Comments:** We agree that the NCPDP Provider Identifier should continue to be used to identify pharmacies until such time as the NPI is fully implemented and available for use. We do not agree, however, with the recommendation that the NCPDP HCIdea be used in the event that the National Provider System (NPS) cannot enumerate providers (prescribers) in time for Medicare Part D electronic prescription drug program implementation. Rather, as stated above, we recommend the continued use of existing network identifiers for prescribers, such as the SureScripts SPI, until such time as the NPI is in fact ready for general use.

*CMS: Formulary and Medication History Standards. The NCVHS noted that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub, a national formulary and benefits information exchange. In response to industry testimony, RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be*

*considered for adoption as an ANSI-accredited standard. NCVHS considered ANSI accreditation to be a criterion in their recommendations process, and HHS proposes to adopt this as a criterion for determining adequate industry experience.*

*The NCVHS recommended that HHS actively participate in and support the rapid development of an NCPDP standard for formulary and medication history using the RxHub protocol as a basis, and indicated its belief that this appeared possible in time to adopt the standard as a foundation standard.*

*We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. We would consider adopting an NCPDP standard for formulary and medication history that are based on the RxHub protocol.*

*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and point-of-care (POC) vendors.*

*The standards provide a uniform means for--*

*+ Pharmacy benefit payers (including health plans and PBMs) to communicate a range of formulary and benefit information to prescribers via POC systems; and*

*+ POC vendors to receive a range of formulary and benefit information through these services.*

*The standards cover a range of formulary and benefit data, including information on the--*

*+ Formulary (for example, therapeutic classes and subclasses);*

*+ Formulary status (for example, drugs that the benefit plan considers to be ``on formulary'');*

*+ Preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and*

*+ Copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another).*

*We propose the following critical characteristics for medication history standards:*

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and POC vendors.*

*The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*

*The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe,*

*and may include the pharmacy that filled the prescription and the physician that wrote the prescription.*

**SureScripts Comments:** SureScripts understands and appreciates CMS's strong interest in adopting standards that would enable the transmission of formulary representation and medication history information within the MMA electronic prescribing program as soon as possible. Great progress has been made in this area over the last six months, and a proposed standard appears that it will be adopted by an ANSI-accredited SDO (NCPDP) in the near future. However, because this standard will not have had widespread usage among a broad variety of industry participants, CMS should carefully consider whether adequate industry experience exists with this new standard to warrant its quick adoption as an MMA foundation standard or whether it should first be pilot tested in 2006.

*CMS: Drug Information. Section 1860D-4(e)(2) of the Act specifies that an electronic prescription drug program will include information on drug-drug interactions, warnings or cautions, and when indicated, dosage adjustments. Given that relevant e-prescribing standards must permit electronic exchange of drug labeling and drug listing information maintained by the FDA and the NLM, medication history standards should be compatible with those standards when they are adopted by the Secretary. While drug information standards will not be foundation standards, they will be supported in the future by the structured product label. While standards for providing this type of information on drugs have not yet been considered by the NCVHS and are not yet proposed, we anticipate proposing standards in the future through rulemaking because they are required by MMA and we believe that providing this information is essential to improving the safety and quality of medication management. We invite public comment on standards that should be required to support an electronic prescription drug program required under the Part D benefit.*

**SureScripts Comments:** SureScripts does not have a recommendation to make at this time with regard to drug information standards, but we would like to be apprised of any such standards that CMS does propose in the future through the rulemaking process so that we might comment on them when appropriate. In addition, we strongly believe that any drug information standards recommended for use by CMS, either in proposed or final rules, should absolutely be thoroughly tested first in a wide variety of industry settings prior to being recommended.

H. Summary of Status of Standards for an Electronic Prescription Drug Program

*CMS: We recognize that the standards we are proposing do not provide all of the functions for which standards are required by section 1860D-4(e)(2) of the Act. At this time, we can only propose to adopt, as final standards, those standards with which there is adequate industry experience; otherwise, pilot testing is required by section 1860D-4(e)(4)(c) of the Act prior to the adoption of a standard as a final standard. We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In*

*addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

*The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

*The ASC X12N 270/271--Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

*The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to as the NCPDP Telecommunication Standard).*

**SureScripts Comments:** SureScripts agrees with and wholeheartedly supports CMS's proposal to adopt the NCPDP SCRIPT Standard, the ASC X12N 270/271 Transaction, and the NCPDP Telecommunication Standard as foundation standards for the electronic prescribing program created by the MMA, provided that the versions listed above are considered minimal version levels, and business partners may utilize newer versions as described in our response on versioning that we provided above in Section F. We are particularly pleased with the recommendation that the NCPDP SCRIPT Standard be adopted as a foundation standard because of its near-universal acceptance and use by participants in the ambulatory electronic prescribing environment nationwide.

In addition, SureScripts is completely comfortable with the strategy that CMS is proposing of phasing in implementation of an electronic prescription drug program by requiring participants to comply initially with the proposed foundation standards listed above, and at a future date, to comply with other necessary standards, provided that they are adopted using a similar rulemaking process and are subject to pilot testing if they do not have adequate industry experience.

*CMS: We acknowledge that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive Electronic Health Record (EHR) system with decision support functionality and must be interoperable with other functions of an EHR. The need for interoperability between these*

*systems will become even more critical in the future when patient medical history standards are adopted. While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that are ANSI-accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

**SureScripts Comments:** SureScripts agrees with the reasoning behind CMS's approach of adopting foundation electronic prescribing standards that are ANSI-accredited and have adequate industry experience as a means of facilitating interoperability with EHRs. SureScripts already is transmitting electronic prescriptions and refill renewal requests and authorizations back and forth between a number of EHR application providers and pharmacy partners. We believe that prescribers will continue to need to use a variety of portals to gain access to the electronic prescribing infrastructure, and we are committed to expanding the interoperability of all of these systems at every opportunity.

II. Provisions of the Proposed Regulation, C. Proposed Requirements for Part D Plans

*CMS: Many closed networks, such as staff-model HMOs, currently conduct e-prescribing within the confines of their enterprise. They typically use HL7 messaging whether it is for computerized physician order-entry within a hospital or for a prescription transmitted to the organization's own pharmacy. The e-prescribing standards that these ``closed'' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards.*

*It is important to note that the NCVHS recommendation differs from the HIPAA transaction requirements. The preamble for the Transactions Rule (65 FR 50316-50317) discusses transmissions within a corporate entity requires covered entities to use the adopted transaction standards when conducting covered electronic transactions with other covered entities. The Transactions Rule also expressly states that if a covered entity conducts a covered transaction using electronic media within the same covered entity, it must conduct the transaction as a standard transaction (45 CFR 162.923). Consequently, whether the transaction is conducted within or outside the entity is immaterial with respect to whether compliance with the HIPAA transactions is required.*

*This issue is relevant to Medicare Part D in situations where an MA-PD plan, for example, is a staff-model HMO using an internal pharmacy. We solicit comment on whether Part D plans*

*should be required to use the standards for e-prescribing transactions within the enterprise, the potential implications (including timing) of required compliance with adopted standards for these transactions, the extent to which these entities exist, and the advantages and disadvantages associated with excluding these transactions from the requirement to comply with adopted e-prescribing standards.*

**SureScripts Comments:** We agree that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise. However, NCPDP and HL7 have worked together to ensure that the content of NCPDP and HL7 transactions are compatible for outpatient prescriptions and we believe this to be a viable solution in the near term. The SureScripts electronic prescribing network is now able to receive HL7 prescription transactions and convert them into the NCPDP SCRIPT format for transmission to community pharmacies. We are pleased to offer this value-added service to our partners, because we believe it supports the earlier adoption of electronic prescribing particularly by inpatient clinical systems and ambulatory Electronic Medical Record (EMR) solutions. We would prefer that this not be considered a long-term solution for moving electronic prescribing messages "outside of the organization" (i.e. from EMR solutions in a clinic or hospital setting to community pharmacies). Rather, we would like this to be viewed as a transitional approach, one that should only be allowed for a reasonable period of time. We recommend that technology companies that have implemented electronic prescribing by January 1, 2006 using this exemption be allowed one additional year to bring their systems into compliance with the NCPDP SCRIPT standard.

E. Proposed Standards

*CMS: The Secretary has tentatively concluded that the proposed standards discussed below are not subject to pilot testing because adequate industry experience with these proposed standards already exists. Entities with electronic prescription drug programs would be required to comply with the proposed applicable standards no later than January 1, 2006.*

*1. Prescription*

*The NCPDP SCRIPT Standard contains a series of business processes, referred to as transactions, which are included in the NCPDP SCRIPT Standard. We propose to adopt, as part of the proposed foundation standards, the transactions included in the NCPDP SCRIPT Standard Implementation Guide, except for the Prescription Fill Status Notification Transaction (and its three business cases: Prescription Fill Status Notification Transaction--Filled; Prescription Fill Status Notification Transaction--Not Filled; and Prescription Fill Status Notification Transaction--Partial Fill). This transaction will not be adopted at this time because, as discussed during the NCVHS hearings, we do not believe there is adequate industry experience with the standard. This transaction and its associated business cases are identified in sections 6.11 through 6.14 and described on pages 40 through 45 of the Implementation Guide, Version 5.0.*

*We propose, in new Sec. 423.160(b)(1), to adopt the following transactions of the NCPDP SCRIPT Standard, for communication of prescription information between prescribers and dispensers, as part of an electronic prescription drug program:*

*New prescription transaction*
*Prescription refill request and response transactions*
*Prescription change request and response transactions*
*Cancel prescription request and response transactions*
*The following ancillary messaging and administrative transactions:*
*+ Get message transaction*
*+ Status response transaction*
*+ Error response transaction*
*+ Verification transaction*
*+ Password change transaction*

*We do include, as part of the proposed foundation standards, the previously identified ancillary messaging and administrative transactions. These transactions are an integral part of the NCPDP SCRIPT Standard, providing the administrative functions to assure that prescription transactions are accurately exchanged. Industry experience with the adopted HIPAA transactions has shown the need for standard acknowledgement and error reports transactions. During the NVCHS hearings, the only transaction specifically mentioned as lacking industry experience was the Prescription Fill Status Notification Transaction and, thus, it has not been included in this proposed rule. Because these ancillary messaging and administrative transactions are an integral part of the NCPDP SCRIPT Standard, we believe that the industry has adequate experience with them, so as to be able to forego pilot testing. We solicit public comment on the adoption of the ancillary messaging and administrative transactions in the NCPDP SCRIPT Standard as proposed foundation standards and whether there is adequate industry experience to forego pilot testing.*

**SureScripts Comments:** Again, SureScripts agrees with CMS's proposed adoption of the NCPDP SCRIPT Standard as a foundation standard for the MMA electronic prescribing program. There is no question that there is adequate industry experience with both the new prescription and the prescription refill request and response transactions, and though not used nearly to the same extent thus far, we are also comfortable with including both the prescription change request and response and the cancel prescription request and response transactions among the MMA foundation standard recommendations. Further, we do believe that there is adequate industry experience such that the associated ancillary messages should be able to forego pilot testing. (As an aside, it should be noted that the use of SCRIPT ancillary messages should not be required, because there are instances in which they are not necessary. For example, there are some implementations that do not require a GET message since mail boxing is not required.)

*CMS: If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which*

*provides for publication in the Federal Register of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

*When determining whether to waive notice and comment and whether to incorporate by reference multiple existing versions, we would consider the significance of any corrections or revisions to the standard as well as whether the newer version is ``backward compatible'' with the previously adopted version. In this context, we intend the term ``backward compatible'' to mean that the newer version would retain, at a minimum, the full functionality of the version previously adopted in regulation, and would permit the successful completion of the applicable e-prescribing transaction with entities that continue to use the previous version. We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR parts 160 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. <u>We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification</u>.*

**SureScripts Comments:** SureScripts would agree with this procedure as long as the HIPAA standard modification would not cause electronic prescribing standards to be "locked in" or have to return to an older version. Our belief is that electronic prescribing standards will be more advanced than applicable HIPAA transaction standards due to the process required to change HIPAA transaction standards.

<u>IMPACT ANALYSIS</u>

A. Overall Impact

*CMS: We anticipate that the use of the standards proposed in this rule, and the fact that we are proposing that these standards be available for the January 2006 implementation of the Medicare Prescription Drug Program, will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used. While there are no detailed models predicting specific rates of adoption for this technology, based on our sense of the likely expert consensus, we think it likely that the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years. The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of--*

*Publicity surrounding the Medicare Prescription Drug Program;*

*More publicity about the benefits of e-prescribing and the experience of prescribers who are participating;*
*Increased emphasis on health information technology in general;*
*Potential cost savings to providers using e-prescribing; and*
*The availability of incentives for participation.*

*We believe that as prescribers gain experience with e-prescribing, they will recognize the benefits and share those experiences with colleagues. We invite public comment on our expectations for prescriber participation.*

**SureScripts Comments:** We believe that CMS's expectations for prescriber participation in electronic prescribing are actually much too conservative. For example, a recent report released by the Pri-Med Research Group showed that among the primary care practitioners surveyed, more than one in five reported using e-prescribing systems now, and another 42 percent said they were planning to do so in 2005. In addition, a recent Medical Economics survey indicated that one in four prescribers plans to buy an EMR system soon, at least 70 percent of which already include electronic prescribing functionality.

*CMS: We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis. We plan to publish a more complete impact analysis in the final rule, including an assessment of impacts on the Medicare program, the effect on Part D spending, annual savings to Medicare, costs to plans and providers, and estimated costs and savings for the private sector and other Federal programs.*

**SureScripts Comments:** SureScripts has created an Industry News Search Engine that can be found on our web site that will be of great assistance to CMS as it compiles data for all of the subjects of this Impact Analysis. Well over 100 news reports and articles can be searched using this engine, which is located at http://www.surescripts.com/MRRC/topic.asp

C. Impact on Prescribers

*CMS: We invite public comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing. We also anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance.*

**SureScripts Comment:** We do not have any direct information on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing (other than what

might be available through our Industry News Search Engine, which is discussed above), but we do believe in the benefits of incentives to prescribers such as pay-for-performance programs that have been contemplated by CMS and other private payers, so long as said programs do not include inappropriate messaging done with the intent of benefiting the provider of the incentive programs.

*CMS: There is anecdotal evidence of direct economic benefits that accrue to prescribers that implement e-prescribing, in addition to the previously discussed health benefits to patients. The following examples of these benefits have been reported:*

*A 53 percent reduction in calls from, and a 62 percent reduction in calls to, the pharmacy.*

*Time savings of one hour per nurse and 30 minutes per file clerk per day by streamlining medication management processes.*

*A large practice in Lexington, Kentucky estimates that e-prescribing saves the group $48,000 a year in decreased time spent handling prescription renewal requests.*

*Prior to implementation of e-prescribing, a large practice in Kokomo, Indiana with 20 providers and 134,000 annual patient office visits was receiving 370 daily phone calls, 206 of which were related to prescriptions. Of the 206 prescription-related calls, 97 were prescription renewal requests. The remainder consisted of clarification calls from pharmacists or requests for new prescriptions. Staff time to process these calls included 28 hours per day of nurse time and 4 hours per day of physician time. Chart pulls were required in order to process half of the renewal requests. Implementation of an e-prescribing system produced dramatic time savings that permitted reallocation of nursing and chart room staff.*

*Potential reductions in malpractice insurance because of improvements in the quality of patient care resulting from better tracking of patients' drug regimen and a reduction of ADEs, which may occur with e-prescribing.*

*These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.*

**SureScripts Comments:** We again direct you to our Industry News Search Engine on our web site, which should provide you much additional information on actual and potential savings to prescribers who use electronic prescribing: http://www.surescripts.com/MRRC/topic.asp

D. Impact on Pharmacies and Other Dispensers

*CMS: Testimony from pharmacists and professional pharmacy organizations provided to the NCVHS (available on the Web at http://www.ncvhs.hhs.gov reported the following benefits of e-prescribing for pharmacies:*

*Reduced time-consuming phone calls to physicians.*

*Improved accuracy and less time for refill authorizations.*

*Additional time available for patient contact and services.*

*Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).*

*Improved turnaround time for refill authorizations.*

*We do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing. While we expect to see the efficiencies (discussed at the beginning of this section) at pharmacies with some possible reductions in administrative staff time, we do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program. The industry has provided information indicating that 75 percent \8\ of the 57,208 pharmacies in the U.S. already have e-prescribing capability which suggests that pharmacies already find this a beneficial investment. In this respect, we note that the great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small. For example, as indicated earlier in this preamble, we believe that over 95 percent of pharmacy systems are already compatible with the NCPDP retail pharmacy drug claim standard. Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive. We do, however, request additional information on pharmacy impacts.*

**SureScripts Comments:** We agree with CMS's assessment of the benefits of electronic prescribing for pharmacies. On the other hand, we believe that CMS has underestimated the cost for pharmacies to adopt and utilize electronic prescribing capabilities. The cost to add electronic prescribing functions to a community pharmacy involves both upfront costs and ongoing transaction fees. While it is true that most chain pharmacy organizations and the pharmacy software vendors that serve independent pharmacies have absorbed these upfront costs in order support the development of the electronic prescribing infrastructure, there still will be significant ongoing costs involved when pharmacies actually use the infrastructure. SureScripts has observed transaction fees in the community pharmacy marketplace ranging from $0.215 to $0.35 (note that one fee is charged when a pharmacy receives an electronic prescription and just one fee is charged for a message to the prescriber and any response on refill renewal requests). It is important to understand that community pharmacies are paying all transaction costs related to electronic prescription messages. We are not aware of any business models that require physicians to share in the transaction costs associated with electronic prescribing. Thus, though it is difficult to make highly accurate predictions at this time, it is quite reasonable to suggest that the average community pharmacy might incur electronic prescribing transaction fees that total $4,000 to $5,000 per year.

I. Conclusion and Alternatives Considered

*CMS: For the reasons given above, we are not preparing analyses under the RFA, section 1102(b) of the Act, or the Unfunded Mandates Reform Act. We have, nevertheless, considered the alternatives discussed below. We welcome comments on ways to lessen any unforeseen burden of our proposals, on alternatives that might be more effective or less costly, and on any other improvements we can make before issuing a final rule.*

*Two sets of standards that we are proposing in this rule already are required standards under the Administrative Simplification provisions of HIPAA. The ASC X12N270/271--Health Care*

*Eligibility Benefit Inquiry and Response and NCPDP Telecommunication Standard are adopted standards and required when conducting standard transactions. We are proposing these standards for e-prescribing because they are already adopted standards for HIPAA transactions and meet some of the requirements specified in Title I, section 1860D-4(e) of the Act, as amended by section 101 of the MMA.*

*The NCPDP SCRIPT Standard is in widespread use and meets many of the e-prescribing requirements outlined in section 1860D-4(e) of the Act. Also, NCPDP is developing NCPDP SCRIPT transactions to meet other MMA requirements for future consideration or pilot testing. The NCVHS did not recommend any viable alternatives for e-prescribing foundation standards because testimony presented by the industry during the NCVHS hearings strongly supported the NCPDP SCRIPT Standard (available on the Web at http://www.ncvhs.hhs.gov).*

*An alternative to adopting these particular standards as final foundation standards for e-prescribing would be to pilot test the recommended standards. The NCVHS did not recommend pilot testing for these foundation standards because they are already adopted standards with adequate industry experience.*

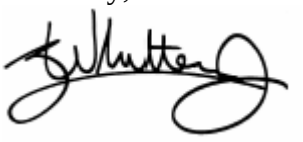
*Another alternative considered would be to adopt formulary and medical history standards based on proprietary standards that are not ANSI accredited. If the coalition developing these standards is successful with the accreditation process and there is evidence of adequate industry experience with these standards, the standards could be adopted in the final rule. We would consider including a functional equivalence standard in the final rule if a reasonable one could be devised. However, the standards proposed allow alternatives, as long as the informational content and format are comparable.*

**SureScripts Comments:** As noted above, SureScripts commends CMS for proposing to adopt the NCPDP SCRIPT Standard, the ASC X12N 270/271 Transaction, and the NCPDP Telecommunication Standard as foundation standards for the electronic prescribing program created by the MMA. We strongly believe that this was the appropriate course for CMS to take given the current state of the industry and the requirements made by the MMA. We see no valid reasons to consider the alternatives of first pilot testing these proposed foundation standards, and we would discourage CMS from delaying the timely adoption of these standards in order to so.

## Conclusion

SureScripts appreciates the opportunity to continue to provide advice and assistance to CMS as it works to implement the electronic prescription program requirements of the MMA through this proposed rule. We hope CMS will continue to take advantage of the experience that SureScripts can share with respect to the real-world implementation of electronic prescribing for the purposes of improving the safety, efficiency, and quality of the overall prescribing process. Please do not hesitate to have your staff contact us should they have any questions regarding the comments we have offered above or if the are any other ways that we can assist them in this important work.

Sincerely,



Ken Whittemore, Jr.
VP, Professional and Regulatory Affairs

ken.whittemore@surescripts.com
(703) 921-2114

Attachment

**SureScripts Recommended Rules to Prohibit Inappropriate Messaging in Electronic Prescribing Systems and Transactions**
**MMA Electronic Prescribing NPRM**

(a) *General*. Part D sponsors and their subcontractors, pharmaceutical manufacturers, pharmacies, and vendors of e-prescribing technology shall neither permit nor engage in inappropriate messaging in the establishment, maintenance, and operation of e-prescribing technology or an electronic prescription drug program.

(b) *Penalties.* Violations of this section shall be subject to Intermediate Sanctions as described in section 423.750.

*c) Definitions and Guidelines*

1. *Definitions*
   a. "Prescribing decision" means a physician's decision to prescribe a certain Part D drug or direct the patient to a certain pharmacy.
   b. Point of care refers to the time, commencing upon the physician's review of a patient's medical record and terminating upon the physician's signature on the prescription, during which a physician or his/her agent is engaged in the act of prescribing a Part D drug for a patient.
2. Except as specified paragraphs (4) and (5), Technology Vendors shall not use, alter, or modify their systems in any manner that would direct, influence, or encourage a physician or patient, at the point of care, to prescribe, select, or use a specific Part D drug or pharmacy, as compared to other Part D drugs or pharmacies.
3. Technology Vendors shall not use any means, program, or device, or knowingly permit any other person to use any means, program, or device, including, but not limited to, advertising, instant messaging, and interruptive messaging (e.g., "pop up" ads), to direct, influence or attempt to direct or influence, through economic incentives or otherwise, the prescribing decision of a physician at the point of care, or to make more difficult or unduly burden a physician's or patient's selection of a particular pharmacy or Part D drug as compared to another pharmacy or Part D drug if such means, program, or device (as described above) is triggered by, initiated by, or in specific response to, the input, selection, and/or act of a physician or his/her agent prescribing a Part D drug or selecting a pharmacy for a patient
4. Notwithstanding the above, Technology Vendors may display or present information regarding a Part D plan's formulary and benefit design, including lower cost Part D drug and pharmacy options, the tier placement of Part D drugs, prior authorization, step therapy, coverage status, and co-payment information, even if such information influences the patient or physician's choice of pharmacy or other prescribing decisions, so long as (i) such display or presentation is neutral and unbiased and the source of the information is identified, (ii) the End User may access all Part D drugs known through generally available sources used in the industry, and all pharmacies including all retail and mail service pharmacy options available, and (ii) nothing is designed to preclude a physician or patient from selecting any particular pharmacy or Part D drug.
5. Additionally, any lists created and maintained by End Users within a Technology Vendor's software product including, but not limited to, (i) an individual End User's list

of most frequently prescribed Part D drugs, (ii) an individual End User's list of most frequently used pharmacies, (iii) an individual End User's most frequently used SIGs (i.e., instructions for the use of medications), would not be considered a violation of this Section.

**Submitter :** **Mr. Rich Johnson** **Date: 04/05/2005**

**Organization :** **Texas Medical Association**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-68-Attach-1.DOC

CMS-0011-P-68-Attach-2.DOC


April 5, 2005

Mark B. McClellan, M. D.
Administrator
Centers for Medicare and Medicaid Services

Re: 42 CFR Part 423 [File Code CMS-0011-P] RIN-0938-AN49

Dear Dr McClellan,

On behalf of the 40,000 members of Texas Medical Association, thank you for the opportunity to offer comments on Medicare Part D. Our members continue to follow the implementation of this sweeping initiative with interest and concern. In supporting the comments of the American Medical Association on the first phase of rulemaking re: electronic prescribing/related issues, we are committed to a regulatory framework for Medicare Part D that serves the interests of beneficiaries and their physicians in providing the best quality health care possible.

In anticipating the startup of the program in 2006, we remain concerned that the possibility of limiting needed medicines and therapies is a real one, presenting the same problems with access to care for Medicare beneficiaries that we have seen overall in our state's commercial marketplace during the last decade. Part D will be a historic expansion of health care delivery in this setting of care, and deficits in care delivery related to prescription drugs could encumber rather than enhance beneficiaries' access to care.

In the interest of promoting the broadest access possible to high quality health care, we support comments to be submitted separately by the AMA on proposed rules for e-prescribing and related issues that continue implementation of Medicare Part D. This component of rulemaking is especially critical as physicians gear up for the changes in their practices prompted generally by new health information technology and e-prescribing in the Medicare program in particular. Of special significance to beneficiaries and physicians are current voluntary provisions of Section 101 of the Medicare Modernization Act that we feel must remain intact if the e-prescribing standards and related requirements specified in Part 423 of the proposed rules are to be effective. Of equal importance is TMA's strong belief that the regulatory structure growing out of this proposal should not take options away from physicians and patients to select drug therapies that are both therapeutic and cost effective. While accurate formulary information helps inform physicians and patients, formulary presentation should not be used to exert untoward influence on the prescribing process. In that same regard, e-prescribing should not foreclose physicians' prescribing options before they have been informed of a complete range of choices. We urge your serious consideration of AMA comments to be submitted to CMS today.

As proposed rulemaking continues into its next phases, we also urge CMS to address the following concerns and issues.

-TMA supports the utmost transparency and public accountability in the organization, functioning and documentation of the work of so-called P&T Committees. Our members are concerned that absent full disclosure of data sources, methodologies and descriptions of deliberative processes of P&T Committees there will be barriers to identification of needed therapies and to information physicians need to advocate for and provide the best care to beneficiaries.

-Part D should specify appeal mechanisms that are easy for beneficiaries to initiate and use. If complex written protocols are implemented, the goal of assisting beneficiaries and their physicians to seek the most cost-effective care available could be compromised. Additionally, there should be provisions that allow alternative arrangements for a short-term supply of a beneficiary's drug of choice until an appeal is complete and a decision is final.

-TMA supports coverage provisions that more simply and fully explain how beneficiaries are notified of proposed changes in drug therapies, how relative costs impact the availability of certain medicines for low income beneficiaries and those dually eligible for Medicare and Medicaid. Our members are also concerned that any requirements for prior authorization may functionally limit clinically appropriate options for beneficiaries and their treating physicians.

-The involvement of state and specialty societies in the development of a formulary for this program will be essential. By identifying and engaging physicians with expertise in this area from such state and specialty organizations, CMS could address problems with a potential lack of both transparency and specificity of process in inventorying best practices and the most current standards of care. Additionally, physicians from state and specialty organizations, working with Medicare Quality Improvement Organizations, are in the best position to assist CMS in developing strategies for physicians to use in promoting patient safety and liability risk reduction overall in the implementation of Medicare Part D.

Again, thank you for the opportunity to comment. TMA will be actively engaged on behalf of Texas patients and their physicians in advocating for regulatory policies that truly reflect the intent of Congress in the largest expansion of Medicare since it's inception in 1965. We look forward to opportunities to work with you and CMS to that end.

Sincerely,

Bohn D. Allen, M. D.
President


April 5, 2005

Mark B. McClellan, M. D.
Administrator
Centers for Medicare and Medicaid Services

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In the interest of promoting the broadest access possible to high quality health care, we support comments to be submitted separately by the AMA on proposed rules for e-prescribing and related issues that continue implementation of Medicare Part D. This component of rulemaking is especially critical as physicians gear up for the changes in their practices prompted generally by new health information technology and e-prescribing in the Medicare program in particular. Of special significance to beneficiaries and physicians are current voluntary provisions of Section 101 of the Medicare Modernization Act that we feel must remain intact if the e-prescribing standards and related requirements specified in Part 423 of the proposed rules are to be effective. Of equal importance is TMA's strong belief that the regulatory structure growing out of this proposal should not take options away from physicians and patients to select drug therapies that are both therapeutic and cost effective. While accurate formulary information helps inform physicians and patients, formulary presentation should not be used to exert untoward influence on the prescribing process. In that same regard, e-prescribing should not foreclose physicians' prescribing options before they have been informed of a complete range of choices. We urge your serious consideration of AMA comments to be submitted to CMS today.

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Again, thank you for the opportunity to comment. TMA will be actively engaged on behalf of Texas patients and their physicians in advocating for regulatory policies that truly reflect the intent of Congress in the largest expansion of Medicare since it's inception in 1965. We look forward to opportunities to work with you and CMS to that end.

Sincerely,

Bohn D. Allen, M. D.
President

**Submitter :** **Mrs. Diana Dennett** **Date: 04/05/2005**

**Organization :** **AHIP**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment

CMS-0011-P-69-Attach-1.DOC

**America's Health Insurance Plans**

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.org


April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

## Application of Standards Within Organizations

***Issue:*** The standards should not be applied to electronic prescribing communications within a "closed network."

***Discussion:*** The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan…." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity are not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

***Recommendation:*** AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS either reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103) or adopt the following language:

*A "closed enterprise" is:*

*1. A clinically integrated care setting in which individuals typically receive health care from more than one health care provider that share a common electronic health information system;*
*2. An organized system of health care in which more than one covered entity (as defined by HIPAA) participates and in which the participating covered entities:*
- *a. Hold themselves out to the public as participating in a joint arrangement; and*
- *b. Participate in joint activities that include at least one of the following:*
  - *i. Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf; or*
  - *ii. Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; and*
- *c. Share a common electronic health information system.*

## Pilot Testing

***Issue:*** Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

***Discussion:*** The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations, varying transaction volumes and system capabilities, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

***Recommendation:*** AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

## Standards for Formulary Representation and Medication History

***Issue:*** The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

***Discussion:*** The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the

[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).

RxHub protocol as a basis for these standards. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA approved standards development organization.

NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history. Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested and implemented.

***Recommendation:*** AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

**Process for Modifying the Standards**

***Issue:*** The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

***Discussion:*** The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, CMS should consider the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to CMS which should release them as an interim final rule with a 60 day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted and implemented to allow any necessary changes to technology and business systems.

***Recommendation:*** AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

**The National Provider Identifier**

***Issue:*** Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

***Discussion:*** The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

***Recommendation:*** AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.

**State Law Preemption**

***Issue:*** The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

***Discussion:*** The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

***Recommendation:*** AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

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[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

**Submitter :** **Mr. Anthony Schueth** **Date: 04/05/2005**

**Organization :** **Point-of-Care Partners, LLC**

**Category :** **Other**

**Issue Areas/Comments**

**GENERAL**

GENERAL

We have attached our response to the NPRM.

**Submitter :** **Dr. Judith Kashtan** **Date: 04/05/2005**

**Organization :** **Private Practice**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

There are two problems with this proposal for electronic prescribing. (1) It forces all physicians who engage in electronic prescribing to become covered entities under HIPAA and (2) it ignores the fact that nation's electronic information systems are highly vulnerable to hacking and corruption.

With respect to HIPAA, the Amended Privacy Rules allows the release of personal health information without patient consent for the purposes of treatment, payment and health care operations. This is allowed in spite of the fact that the Department of Health and Human Services has noted, ??the entire health care system is built upon the willingness of individuals to share the most intimate details of their lives with their health care providers?.More than anything else, the relationship between a patient and a clinician is based on trust.' HIPAA legalizes violation of this trust which is prohibited by professional ethics. Therefore increasing the number of physicians who are covered entities under HIPAA will increase the number of patients who are at risk to have their privacy legally violated.

With respect to the lack of security with the use of electronic prescribing, the findings of the President's Information Technology Advisory Committee show that electronic information systems are highly vulnerable to hacking and corruption, the vulnerabilities are increasing at a rate of 20% a year, and the vulnerabilities cannot addressed without redesigning the information systems from the ground up to build in security measures. 'Cyber Security: A Crisis of Prioritization' (February 28, 2005).

**Issues**

Background

There are two problems with this proposal for electronic prescribing. (1) It forces all physicians who engage in electronic prescribing to become covered entities under HIPAA and (2) it ignores the fact that nation's electronic information systems are highly vulnerable to hacking and corruption.

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**Submitter :** **Mrs. Alissa Fox** **Date: 04/05/2005**

**Organization :** **BCBSA**

**Category :** **Health Care Professional or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

"See Attachment"

**Issues**

Background

Attention: CMS-0011-P, Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people ? nearly one-in-three Americans ? among them approximately one million beneficiaries in Medicare Advantage.
BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries ? and also help slow the rate of growth in spending ? by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.
First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard. CMS should allow a period of pilot testing before final adoption of standards ? as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange ? and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).
? BCBSA supports CMS choices of ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, many commercial and proprietary e-prescribing systems currently do not use these standards. It will take time to develop and deploy software that uses these standards, time to test these standards, and time to identify and correct any problems integrating 270/271 and NCPDP standards.
?Performance testing is particularly important for the 270/271 standards because relatively few providers are now originating 270 transactions for claims. For example, 2004 data on HIPAA transactions from Blue Cross and Blue Shield Plans? national accounts and traveling members show that 270 transactions comprised less than 2 percent of total HIPAA transactions.
?For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

In addition to changing the compliance date, BCBSA urges CMS to make two other important changes:
?Adopt a broader view of preemption that federal law preempts any state law. CMS?s narrow interpretation of preemption could make e-prescribing administratively difficult for providers, pharmacies, and administrators.
? Follow the NCVHS recommendation that an organization?s internal communications not be covered by the rule. CMS?s proposal unnecessarily regulates entities? internal processes, thus raising the administrative burden of supporting e-prescribing.
We appreciate the opportunity to offer these comments, which we strongly believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit. Please see attached.

CMS-0011-P-72-Attach-1.DOC

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

**Blue Cross Blue Shield Association Comments on**
**"Medicare Program: E-Prescribing and the Prescription Drug Program"**
**Proposed Rule**
**NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)**
**CMS-0011-P**

**April 5, 2005**

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific "issue identifier" that precedes the section: **Background;** and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on February 4, 2005.

## I. Background

**State preemption (Page 6258)**

**Proposed Rule:** The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

**Issues:** Variations in state rules and regulations are ubiquitous. As explained in a separate letter "Comments on E-Prescribing of Drugs and Preemption of State Laws," BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

**BCBSA Recommendation:** BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

**Criteria for determining foundation standards (Page 6261)**

**Proposed Rule:** The MMA permits HHS to adopt standards as final without pilot testing where the Secretary can determine there is "adequate industry experience" with the standard. The MMA did not define "adequate industry experience." CMS has proposed the following criteria to assess adequate industry experience:

- American National Standards Institute (ANSI) accredited;
- Generally has been implemented in multiple e-prescribing programs with more than one external partner by entities to which the final standard will apply; and
- Recognized by key industry stakeholders as the industry standard.

**Issues**: We believe that these criteria are necessary – especially ANSI accreditation – but not sufficient to assess adequate industry experience. The HIPAA transaction experience demonstrates that systems and processes vary greatly, especially around key vendor products. Therefore, implementation in "multiple" e-prescribing programs is no guarantee that a standard can go without testing in all settings; for example, systems that work well for a chain pharmacy model may not work well for independent pharmacies or for mail order pharmacies.

**BCBSA Recommendation:** CMS should seek additional recommendations from stakeholders on how to assess adequate industry experience. CMS's view that there is adequate industry experience for the proposed foundation standards – a view that we question – is indicative of the need for added criteria.

**Identifiers (Page 6262)**

**Proposed Rule:** CMS is considering requiring the use of the national provider identifier (NPI) as the provider identifier for an e-prescription under Medicare Part D. The NPI timetable calls for HHS to begin accepting applications from providers for identifiers after May 23, 2005. Use of the NPI is mandatory starting May 23, 2007 (2008 for small health plans).

**Issue:** At this time, it appears that the NPI will not be universally available for use by January 2006. For HIPAA NPI implementation purposes, industry has proposed a "workaround" that would allow transactions to carry both the old identifier and the new NPI. However, provider and vendor systems that send billing information to the Plans may not be able to carry both the legacy identifier and the NPI by January 2006.

Plans that did not expect to have to be ready to process the NPI until 2007 may begin to receive transactions with the NPI as the only identifier and other transactions with a non-NPI identifier. Depending on the source of the transaction, plan systems would have to process the transaction using the NPI or a legacy identifier – running and maintaining duplicate systems for the interim period. Plans must be given sufficient time to migrate providers from their legacy identifiers to the providers' new NPI. Additionally, the NPI does not support the necessary transmission routing functions of electronic prescribing identifiers. Current identifiers allow for individual prescriber identification and multiple service locations. A single identifier solution for this shortcoming must be developed, assessed and tested.

**BCBSA Recommendation:** BCBSA urges that CMS move back the January 1, 2006 compliance date to permit additional time for pilot testing and implementation. This would have

the added benefit of avoiding the issues created by an early implementation of the NPI for e-prescribing.

We note that the Workgroup for Electronic Date Interchange (WEDI) recommended in a September 30, 2004 letter to Secretary Tommy Thompson that no successful implementation of the NPI could occur in less than 18 months from the time the NPI is available for use, and that no full-scale implementation should be undertaken without pilot testing the NPI.[1] We would support pilot testing use of the NPI in the e-prescribing context.

**Formulary and medication history standards (Page 6263)**

**Proposed Rule:** The NCVHS determined that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer Protocols established by RxHub. On the basis of this determination and other criteria revealed in the proposed rule, CMS is proposing to adopt other standards currently under development by NCPDP as foundation standards.

**Issue:** Many Plans that intend to offer Part D benefits use commercial or proprietary formulary and medication history messaging protocols dissimilar to those that will be balloted by NCPDP. Thus, adequate industry experience is lacking.

**BCBSA Recommendation:** CMS should adopt the formulary and medication history standards currently being balloted by NCPDP as initial standards to pilot test and not as foundation standards for required use beginning January 1, 2006.

**Proposed foundation standards (Page 6264)**

**Proposed Rule:** CMS proposes to apply the "adequate industry experience" exception to specific standards regarding prescription transmissions between prescribers and dispensers and eligibility inquiries between dispensers and payors and prescribers and payors (NCPDP SCRIPT Standard, Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5.1; and American Standards Committee (ASC) X 12N 270/271).

**Issue:** BCBSA supports using ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, industry does not have adequate experience because many current commercial and proprietary e-prescribing systems do not use the 270/271 standards. These e-prescribing systems generally provide eligibility information to the pharmacy using the NCPDP telecommunication standard. It will take time to make enrollee eligibility available to physicians using the 270/271 transaction: time for software development; time for deployment; and time to identify and correct any integration problems.

For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

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[1] *See* "WEDI NPIPAG Recommendations, August 26, 2004," Issues 1 and 3. A copy of this correspondence can be found at http://www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/093004NPIFinalEDJR.pdf .

Lack of adequate industry experience may be a particular issue for mail order pharmacies. Communicating eligibility and benefit status to and from a dispensing pharmacy via the NCPDP telecommunications standard is currently a HIPAA required transaction standard for communications with retail pharmacies. But in mail order pharmacies, prescriptions generally arrive via fax and are entered into the mail-order pharmacy's automated fill-order system. Eligibility is determined by checking against enrollee information provided by a plan directly to the mail-order pharmacy and not through an on-line inquiry system built to the NCPDP Telecommunications Standard. These processes operate on computer programs written to code not interoperable with e-prescribing software.

**BCBSA Recommendation:** While BCBSA supports the selection of specific appropriate standards for e-prescribing functions, we urge CMS to support a period of pilot testing (for at least one year) to ensure that the 270/271 standards will perform as desired when integrated into an e-prescribing systems with the NCPDP Telecommunication standards. Also, we urge CMS to provide for an implementation period (the statutory timetable would suggest 24 months) that gives plans sufficient time to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

## II. Provisions

### Definitions (Page 6265)

**Proposed Rule:** CMS proposes the following definition:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

**Issue:** The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

**Recommendation:** BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

### Communication in closed networks (Page 6265)

**Proposed Rule:** CMS would require e-prescribing communications internal to an organization be communicated in compliance with the adopted NCPDP Script standards for e-prescribing for Part D drugs. The NCVHS had recommended that organizations that conduct e-prescribing internally should not be required to convert to the standards to be adopted by CMS for Medicare Part D for prescription communications within their enterprise. CMS notes that the NCVHS

recommendation differs from the HIPAA transaction rule requirement that a "covered entity" conducting a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard HIPAA transaction.

**Issue:** BCBSA is concerned with CMS' decision not to follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. BCBSA's general approach to health information technology is that transaction rules should not dictate internal processing but should ensure standardizing the interfacing between differing organizations' systems for market interoperability.

**BCBSA Recommendation:** CMS should follow the recommendations of the NCVHS and recognize that the exchange of prescription information within the same enterprise is outside the scope of the MMA requirements.

**Backward compatibility (Page 6267)**

**Proposed Rule**: HHS is proposing to consider waiving notice and comment rulemaking when updates or newer versions of standards are "backward compatible" (i.e., entities using the newer version would be able to complete transactions with entities using the the previous version). In this case, CMS would likely permit the version that was previously adopted and the new version as equally compliant at the same time.

**Issue:** In general, an entity using the older version of a standard cannot process the newer version without further system changes, such as the addition of translation software – even when the newer version does not include substantive changes such as new functions. True backward compatibility occurs when the entity adopting the new version pays for the translation software. However, the CMS definition of backwards compatibility could be construed as absolving the entity adopting the new version of the obligation of paying for that translation software, thus inadvertently penalizing entities that choose to keep the previously adopted standard.

**BCBSA Recommendations:** CMS should make clear that the obligation to produce transactions that an entity with a previously adopted versions can process lies with the entity that chooses to migrate to the newer version. CMS should not find backward compatibility where no provision has been made in the standard to ensure that entities with previously adopted versions can process those transactions sent from entities using newer versions.

**Linking e-prescribing standards updates to HIPAA standards updates (Page 6267)**

**Proposed Rule:** CMS proposes to coordinate the updating process for those e-prescribing standards that are also HIPAA transaction standards.

**Issue:** Linking the e-prescribing standard update to the HIPAA standards update would provide administrative simplicity for CMS and reduce the compliance burden for the affected industries and covered entities.

**BCBSA Recommendation:** BCBSA supports having the e-prescribing standards updates tied to the HIPAA updates. This allows entities to monitor one point for future proposed changes. It also avoids getting HIPAA and e-prescribing out of synch and into conflicting requirements.

**Compliance date (Page 6267)**

**Proposed Rule:** CMS proposes making compliance with the e-prescribing standards proposed in this rule mandatory on Part D sponsors and MA/PD plans as of January 1, 2006.

**Issue:** BCBSA believes that January 2006 is not a reasonable compliance date for implementation of these proposed new foundation standards See “Proposed foundation standards” above

**BCBSA Recommendation:** See “Proposed foundation standards” above.

**Submitter :** **Dr. Clement McDonald** **Date: 04/05/2005**

**Organization :** **Regenstrief Institute**

**Category :** **Physician**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-0011-P-73-Attach-1.DOC

Response to NPRM April 5, 2005 – 6:15 p.m. McDonald, CJ

In general there is much to like in this NPRM and I am supportive of most of it. In the following, as an ex-NCVHS'er and a long-term proponent of electronic medical record systems I would like to comment on a number of points.

Page 6258

I would not favor any abbreviation of the testing proposed for these standards. E-prescribing is really a new thing for physician's offices. In such complex undertakings there are always surprises. The better the testing and tuning the better the final product.

Page 6263

The NPI has been under development for more than 8 years in one form or another. Not having a single identifier will be a real problem to this project as well as many other medical informatics developments. So think we should push hard to get the NPI done as a requirement for part D prescribing.

There is not enough information given about the two alternatives proposed in the NPRM- and no statement about cost and who is covered. So hard to comment.

Who is covered by the numbering system could be VERY important. In most offices nurses help with refills and much prescribing management. So what ever approach to prescriber numbering is taken should not prevent office staff from entering refills and / or prescriptions—with some kind of identifier (perhaps local) to identify them and another (national) to identify the prescriber.

Page 6260

Middle column footnote 5

The arguments about the errors and prescribing are quite mixed up. Most of the IOM's death figures related to drugs come from reference 9 on page 1 of the IOM report[1]. This is actually the rate of deaths coded in the death certificate as accidental (not definitely suicide or homicide) related to medications and other noxious substances. One could construe prescribing errors to be some part of the cause. However, the demographics of the people who die in this class are men more than women with 80% between ages 25-49. While those most likely to be injured by prescribing errors would be those who get the most prescriptions – woman and elderly. A recent MMR[2] suggest that 80% of the drugs involved in accidental poisoning as defined above are narcotics and narcotic analogues and the rest are sedatives and antidepressants. A major portion of these cases probably involve acquisition of prescription drugs by illegal means.

The illegible handwriting has not been shown in any large series to be significant contributor to errors—in part because of the 900 million phone calls mentioned in the NPRM that pharmacists make to check such illegible prescriptions.

Finally, regarding 3rd column, 2nd paragraph, just about any of the safety checks that could be done in the office computer can also be done by the pharmacy computer. The big trick is getting the data regarding all other drugs prescribed – relevant diagnoses and lab tests in a unified medical record system.

I bring this up because the one big value a physician (and his/her patients) will get from electronic prescriptions- is a community medication profile, and the problems of linking one patient's prescriptions from many sites have not yet been solved. (See below).

Page 6263 – Medication history

Pharmacies themselves have a very poor infrastructure for creating a medication history. They do not collect enough information routinely to identify the same patient across different pharmacy companies and in some cases between different visits to the same pharmacy. There are better opportunities at the PBM level because they carry much more complete data. The RxHub solution is possible because of PBMs. Having a useful active medication profile—(the way I would like to see the medication history conceived) would be a great value to physicians and an incentive to adopt e-prescribing and medical record systems. As it stands now- physicians will have to load the initial medication profile by hand for every patient they care for. That is a shame when the same data is sitting in pharmacies – but just not inter-connected.

CMS will have to attend to the problem of aggregating the same patient across different prescription providers to provide a really useful medication profile. The best current bet is through PBMs. But with proper attention to a Medicare patient identifier (as contrasted to the beneficiaries' identifier), pharmacies could do better. Be aware of many leakage points. PBMs only know about drugs that they cover. They also only tend to provide information about patients who are currently their members. Given the 30% rate of plan switches per year- this can leave many gaps.

Finally, the NLM RxNorm vocabulary standards with full tie-ins to NDC codes must be part of the medication history standard to produce a useful active medication profile for many reasons.

I support the general direction of the RxHub medication history— as long as a universal clinical drug code, i.e. RxNorm, was used and as long as attention was given to the leakage of key prescription information as described above.

Page 6265

NCPD Script

I support the use of the NCPD script but not as the sole prescription message standard. Hospitals all use HL7 for prescribing information. There is large potential for error in the transfer of patients between settings of care. Providers in hospitals write prescriptions for discharge using their inpatient systems much. Much out patient care is also given by hospital systems. Further, the medications given in the hospital would ideally be incorporated into the

medication history being proposed. Indeed, RxHub currently has a very useful HL7 version of that medication history.

We would propose that HL7 be an allowed electronic message standard for large institutions with the proviso that the coding systems would be aligned with those in the NPRM. HL7 already has a much more sophisticated medication message including structured information about the instructions for dispensing (mentioned on page 6262). Furthermore, NCPD has no ability (yet) to deal with complex home IV and other prescriptions that will tend to be intermixed with oral and other medications in some patients.

HL7 and NCPD are already working toward greater harmonization.

CMS should permit the use of HL7 as an alternative standard for prescriptions written in hospitals and other large organizations and require the two SDO's to harmonize to the degree that they can inter-operate. Then intermediaries could accurately translate from one to the other.

This is the best time to push that harmonization to completion- because it is in the interest of both SDO's and health care in general.

Page 6267

We are supportive of the overall direction, but the current usage of e prescribing by providers is very close to zero (in doctor's offices – per testimony at NCVHS about 1 year ago). On the other hand, it is true that the communication between pharmacists and PBMs through NCPD standards is very high. But am puzzled by the claim that this is "nothing new" (per page 6267- 3rd column) to the physician's offices – targeted by this NPRM. Just hope we are not skipping an important check

Page 6270

It may be that some modest number of (5% or larger) are writing prescriptions, via direct input to computer office practice setting—especially in large institutions and the VA. But a very small percent of these are transmitting them via the proposed standards to commercial pharmacies for a variety of reasons. The testing process should be cognizant of the relative newness of this process.

Clement J. McDonald, M.D.
Director, Regenstrief Institute
Regenstrief Professor of Medical Informatics
and Distinguished Professor of Medicine
Indiana University School of Medicine

[1] Phillips DP, Christenfeld N, and Glynn LM. Increase in US Medication-Error deaths between 1983 and 1993. The Lancet, 351:643-44, 1998.
[2] Morbidity and Mortality Weekly Report url: http://www.cdc.gov/mmwr/

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APR 13 2005

**State of New Jersey**
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
P.O. Box 712
Trenton, NJ 08625-0712
Telephone 1-800-356-1561

RICHARD J. CODEY
*Acting Governor*

JAMES M. DAVY
*Commissioner*

ANN CLEMENCY KOHLER
*Director*

April 4, 2005

Centers for Medicare & Medicaid Services
Department of Health and Human Services
**Attn: CMS-0011-P**
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Medicare Program – E-Prescribing and the Prescription Drug Program
42 CFR Part 423

Dear Sirs:

This letter is in response to your request for comments on the above-referenced proposed regulation regarding E-Prescribing and the Prescription Drug Program which appeared in the Federal Register on February 4, 2005. I am writing to inform you that staff of the New Jersey Division of Medical Assistance and Health Services have reviewed the above-referenced proposed regulations and support the regulation as proposed.

We appreciate the opportunity to comment.

Sincerely,

s: Ann C. Kohler

Ann C. Kohler
Director

ACK:bpw

Sent electronically
BPW

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American Academy of Dermatology Association

1350 I St NW Ste 870
Washington DC 20005-3319
**Phone** 202/842-3555
**Fax** 202/842-4355
**Web Site** www.aad.org

**Clay J. Cockerell, MD**
*President*

**Stephen P. Stone, MD**
*President-Elect*
**Bruce H. Thiers, MD**
*Vice President*
**William P. Coleman, III, MD**
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*Assistant Secretary-Treasurer*
**Ronald A. Henrichs, CAE**
*Executive Director & CEO*

APR 13 2005

April 5, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

FAXED
202-854-9255
CB 9:10Am

RE: Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Dr. McClellan:

On behalf of the 14,000 members of the American Academy of Dermatology Association, I appreciate this opportunity to comment on the proposed rule for electronic prescribing (e-prescribing) standards. These standards represent another important step on the road to developing, promoting, and integrating a national health information technology network for healthcare professionals to provide safe, quality-based, efficient and affordable patient care.

As office-based physicians, dermatologists recognize e-prescribing is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from physician prescribers to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information.

To achieve and maintain these benefits, however, we feel strongly that the proposed federal e-prescribing standards should allow for the operational flexibility and scalability for the prescribing physicians. This would facilitate appropriate management of prescription volume and medication options, especially in ambulatory practices. Furthermore, we urge that the initial e-prescribing standards adopted for the 2006 test pilot project be designed to include the full participation of office-based specialists, including dermatologists, in both rural and urban settings in order to identify and mitigate against any potential health information technology divide and socio-economic disparity that may compromise the quality, safety, and efficiency in the delivery of patient care. Effectively, the results from proposed e-prescribing pilot testing should help address the need for physicians in small and medium-sized ambulatory practices to adopt uniform, user-friendly, and interoperable standards for the provision of safe, quality-based care.

Notwithstanding the promise of e-prescribing, the proposed federal standards should take into account, and promote elimination of prevailing barriers to adoption and usage most common among small and medium-size dermatology practices. These barriers are:

- Cost of purchasing and implementing such a system;
- Lack of interoperable capabilities between healthcare professionals to ensure effective coordination of care;
- Complex and user-unfriendly health information technology that offsets any benefits related to administering quality of care.
- Lack of reliable systems' interface with existing practice systems; and
- Lack of financial incentives for the small business provider;

These significant disincentives need to be addressed and these current obstacles removed in order to promote adoption and implementation by the key, but voluntary participant, the physician.

While the Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care, further consideration must be given to overcoming the above structural, operational and fiscal barriers. Healthcare electronic processes can be beneficial for both patients and physicians and e-prescribing is another step in the right direction.

Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Brett Coldiron, MD, FACP
Chair/AAD Health Care Finance Committee

FAXED
202-842-4339
9:40AM

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
John D. Barnes, Deputy Executive Director, AADA
Judith Magel, Director, Health Policy and Practice, AADA
Laura Saul Edwards, Director, Federal Affairs, AADA
Cyndi Del Boccio, Director, Executive Office, AADA
Norma Border, Senior Manager, Coding and Reimbursement, AADA
Jayna Bonfini, Manager, Political Affairs, AADA
William Brady, Manager, Practice Management, AADA

*Utah Health Information Network* • 151 East 5600 South, Suite 320 • Murray, Utah 84107 • Phone 801-466-7705, Fax 801-466-7169 • www.uhin.com

April 4, 2005

Centers for Medicare & Medicaid Services,
Department of Health and Human
Services, Attention: CMS–0011–P, PO
Box 8014,
Baltimore, MD 21244–8014

Dr McCellan,

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act. As a state-wide network engaged in exchanging administrative information for over 10 years, the UHIN Community was deeply involved in the implementation of the HIPAA transactions and we believe there is a lot to be gleaned from that experience.

**Standards** The first HIPAA lesson is the need for true unambiguous standards. While the NCPCP Script is an admirable standard its implementation will be subject to variation if HHS only adopts the *Standard* HHS should adopt a specific implementation guide of the NCPDP Script. Otherwise, it is likely that grave differences in implementation will arise and interoperability will become a significant barrier to adoption.

**Financial impact.** Second, the UHIN Community believes that implementation of these messages will have a significant *financial impact* upon physicians and pharmacists, especially small physician and pharmacy businesses. HIPAA resulted in vendors charging significantly for both HIPAA upgrades and for the ability to exchange messages. Several large practice management vendors required their customers to utilize certain exchange entities thereby reducing competition in that market. In all likelihood, this will happen again. In all likelihood this will happen again. Thus much of the potential economic incentive to adopt the MMA messages will be eroded, particularly for smaller entities. It is vital that rural hospitals, pharmacies and providers be protected by this economic impact. Utah is largely a rural and frontier state; we cannot afford to lose these critical access entities.

**DEA**. Utah is poised to adopt electronic prescribing. One major barrier is the lack of action on the part of the DEA to designate a legal electronic signature mechanism. The UHIN Community urges HHS to encourage prompt action on the part of the DEA in resolving this issue.

**Privacy** The UHIN Community has expressed some doubts about privacy issues that the proposed exchanges may engender, particularly in the exchange of medication history and medical history. We understand that payers largely have the right to know both the medication and medical history of their members. However, that right does not extend to pharmacists and physicians. The proposed exchange of medical history from any pharmacy and physician to any other would create the need for these entities to know exactly what patient information could be exchanged and what could not. In addition, such an exchange would necessitate the ability to *respond* to an electronic query. This could impose an additional IT burden on pharmacists and physicians.

UHIN appreciates this opportunity to comment on the proposed rules for the Medicare Modernization Act. We believe this act to be a significant step in moving the entire health care community towards exchanging clinical information which will contribute not only to improving patient care and safety, but also potentially reduce health care costs.

Sincerely,

Bart "C" Killian
Executive Director

# Utah Health Information Network

Response to the Medicare Modernization Act Proposed Rules

## I. Background

Comment about:

*Prescribers may not have access to the latest drug knowledge, do not have a completely accurate medication list or do not have a medical history for their patient, and, may be unaware of potential drug-drug or drug-disease interactions or duplicate therapies.*

*Pharmacists often have difficulty reading handwritten prescriptions and have little or no information about the patient's condition for which the prescription is written. May have to contact the prescriber by phone to clarify what is ordered*

*Mak[ing] changes in the prescription results in delays for the patient and time consuming for the prescriber and the pharmacist.*

*Little or no feedback is given to the prescriber on whether a prescription was filled or refilled*

**Comment:**

There was agreement that the current prescribing process is prone to errors. Prescribers do not have easy access to formularies and preferred drug lists; providers do not have easy access to unbiased drug information. Usually both formularies and drug information are printed (and are thus mostly unused). Even when a provider downloads them into software like Epocraties, it often takes too much time to use them on an extensive basis. Hence use of formularies is usually restricted to the provider's top 2 -3 payers and familiarity with drugs is limited to very common drugs.

UHIN providers raised both pro and con points regarding feedback to the provider on whether or not a prescription was filled or refilled. While there was agreement that this information may improve quality of care, some physicians are concerned about additional liability and additional uncompensated work. However, **physicians are in agreement that they do not want to know whether or not a prescription was filled on every prescription they write**. If this information becomes available, they only want to know it about certain prescriptions. It is not efficient for them to have this information about every prescription.

Pharmacists usually do not have a complete list of drugs the person is taking. Usually their only list of drugs a person is taking comes from their own internal data bases. Info on drug-drug interactions from the PBM is spotty at best. Therefore most of the drug-drug intervention is primarily driven off the *pharmacists* data base, not the PBMs. Will the adoption of these messages assist pharmacists in preventing drug-drug interactions? One important point is that there needs to be a system to rate the potential magnitude of a drug-drug interaction; is it minor, moderate or life-threatening?

There seems to be an assumption that the prescriber will have done any medication history checking prior to the patient presenting at the pharmacy. How will the pharmacist know that this has been done? No EDI process is ever 100%; pharmacists need an indicator that medication history has been checked (or not) on incoming prescriptions.

Comment about:

- *"(i) Information on the*
  - *drug being prescribed or dispensed and*
  - *other drugs listed on the medication history, including information on*
    - *drug-drug interactions,*
    - *warnings or*
    - *cautions, and,*
    - *when indicated, dosage adjustments*

**Comment:**

1 Concern was raised about the source of the information on the drug being dispensed

- Would this source of information be neutral or would it be advertising information from the manufacturer?
- Will the drug information data base include negative clinical trials information? Will it include information from the FDA?
- Which data base will be used to monitor potential drug-drug interactions, warnings, and cautions?
- How often will the data base be updated?
- Will all Medicare Part D contractors use the same data base?

The general sense was the different data bases give different information and are more or less reliable

2 Other issues

- Will the PBM be charged with keeping dosage adjustment information? How will they receive this? What about the physicians sample closet –will those types of dosage adjustments be tracked? If yes, how?
- Which message would be used to convey drug-drug interactions, warnings, and cautions?
- Which NCPDP message would be used for drug dosage adjustment information?

Comment about:

*The standards are accredited by an ANSI-accredited standards development organization.*

*The standards permit interface with multiple product, router, and POC vendors.*

*The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*

**Comment:**
Attention was focused on the last bullet which describes an information exchange of medication history between *payers*, *prescribers* and *dispensers* as if all three entities could potentially be data sources. This particular recommendation does not follow the NCVHS recommendation which limited this exchange to prescribers querying PBMs

There was agreement that an expectation that all three parties might be data sources would dramatically increase the complexity and cost of implementation, particularly for dispensers and prescribers.

There was also concern about managing privacy issues if all three entities became data sources. While it is true that if a person holds insurance, there is usually a clause in their contract which states something to the effect that they are allowing the insurer access to their medical information, usually patients who see a need will actively segregate their information so that certain portions of the health care industry do not know all their medical information. However, what if a patient does not want their PCP to know that they had a test for STDs because the PCP is a personal friend of their spouse? While the contract with the payer may require the patient share all medical information with the payer, does it require that the patient share all medical information with ALL their health care providers? There was great concern about the privacy issues such an exchange might open up. While the goal of higher quality care is commendable, should it trump an individuals' right to privacy in all cases?

There was a question about whether large institutions would need to segregate information about inpatient vs ambulatory care. This could be difficult for them to accomplish

Comment about:

*Statute: an electronic prescription drug program includes the electronic transmittal of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed.*

*"Medication history" refers to drugs that have been prescribed to the individual*

*"Medical history" relates more broadly to information about the patient's health care and health status (for example, allergies, laboratory test results, and chronic conditions)*

*Intend to propose standards for communicating medical history at a future date.*

**Comment:**

Concern was expressed about how plans were going to accomplish the statute, namely to transmit medical history related to a Part D drug. This will be difficult to impossible because

- Patients often seen providers for more than one reason (particularly patients in this age group)
- Providers often prescribe drugs for off-label use
- Hence there is no link between the prescription and the diagnosis or problem list.

There was concern expressed about who was going to do Medication Therapy Management? The physician? The PBM? Who?

Comment about:

*"(ii) Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed*

**Comment:**

Concerns were raised about who determines what therapeutically appropriate alternatives are

- The group estimated that many drugs are not used for FDA approved diagnoses (off-label use) How will a payer determine what is a therapeutically appropriate alternative if they do not know what symptoms (presumptive diagnosis?) the drug is being prescribed for?
- Given the relatively common off-label use of drugs, how will a payer, whose primary sources of information on a patient are claims, link prescriptions with claim data?
- Given the relatively common off-label use of drugs, how is a plan to link the use of a Plan D drug with a specific portion of a person's medical history? If a drug is being used for off-label purposes how will a 'therapeutically appropriate alternative" be determined?
- What diagnoses code list would be used? Physicians don't use ICD-9 diagnoses for presumptive diagnoses or for true clinical diagnoses
- Who will make the decision about what is 'therapeutically appropriate"?

Pharmacists would like to get information on which brand of a drug is *cheaper for the particular plan*. They may get indications regarding whether it is permissible to substitute a generic but they still don't know WHICH generic to use; they are not told of any pricing arrangements between plans and pharmacy manufacturers

Comment about:

*"(B) APPLICATION TO MEDICAL HISTORY INFORMATION.--Effective on and after such date as the Secretary specifies and after the establishment of appropriate standards to carry out this subparagraph, the program shall provide for the electronic transmittal ... of information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved*

**Comment:**
What is meant by the term *medical history*? What does this encompass? For example, the medical history of a person with asthma might need to involve such factors as triggers, number of recent exacerbations (or a history of exacerbations), etc. Who will make a determination of what constitutes portions of a medical history that are associated with a specific drug?

There was concern about how a PDP could accurately link medical history (presumably derived from claims). Will the PDP be requiring physicians to respond to inquiries about medical history in order to participate with the plan? Responding to an inquiry about a person's medical history could create an enormous burden upon small to moderate sized physician practices Will there be any compensation for this type of work?

What kinds of standards will be used to make the determination that x portion of a person's medical history is linked with a particular Plan D drug? What about medical history being requested from a physician who did not that another physician had prescribed a certain drug? How is the physician going to know what information to respond with?

Pharmacists pointed out that the data on the prescribing physician that they receive is often inaccurate. This will further challenge the ability of the PDP to link medical data with prescription data when the prescribing physician data is not accurate

**The group strongly recommends *lengthy testing* prior to adoption of any medical history message as well as an *evaluation of the processes* by which the various parties (PDPs, pharmacies, and physicians) might respond to requests for medication history.** Because the rule discussion does not mandate the participation of physicians or dispensers there needs to be extensive testing of the implementation of whatever message is chosen and its impact on the ability of physicians and dispensers to respond. However, one criterion for adoption is that the messages not place an undue burden upon the respondent Medical history could pose an enormous burden to implement

Comment about:

*"(D) TIMING --To the extent feasible, the information exchanged under this paragraph shall be on an interactive, real-time basis*

**Comment:**

There was concern about the phrase "to the extent feasible". If the messages are not done real time, these messages will not be adopted by physicians or pharmacists Real time should be defined as less than a 3 second response

One member of the group has been involved at NCPDP for some time. He mentioned that the Formulary and Benefits message is intended to be a batch download to a formulary repository organization. The UHIN group still wants the query to the formulary repository should be less that 3 seconds. However, the actual message being proposed (the NCPDP Formulary download) would not be a 'real time' message Only the query to the formulary repository would be real time

Physicians often state that they don't want to support the formularies of dozens (sometimes hundreds) of payers. If formulary repository organizations are going to evolve, their use has to be geared towards creating a favorable climate for physicians to use them. For-profit, charge-by-the-query models may face an uphill battle in adoption.

Comment about:

*These proposed foundation standards are a first step toward a more complete set of standards required for an electronic prescription drug program under the MMA*

*Additional final standards will be identified, pilot tested, and proposed through separate processes in accordance with the time frames set forth in the statute and will build on these foundation standards*

*NCVHS recommends that HHS work with the industry through the rulemaking process to determine how best to afford flexibility in keeping current the adopted standards and those adopted in the future*

**Comment:**
Commenters were in agreement that EMRs need to focus on a single standard

There were no comments on State Preemption or on Anti-Kickback or Stark provisions

Comment about:

*HHS believes that it is necessary to have a unique identifier for these transactions*

*The NPI* is the preferred option, because it is a standard that many entities will be required to use under HIPAA*

**Comment:**
UHIN agrees with HHS that these transactions need a unique identifier for prescriber and dispenser. UHIN suggests that HHS stress that EMRs must be able to handle NPI or other types of national identifiers

**UHIN recommends that HHS implement the NPI in synch with the HIPAA schedule.** The NPI must first be proven to be a workable, low-error system before it should be adopted by clinical systems

Comment about:

*ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors*
*Meets Adoption Criteria:*
*ASC X12N 270/271 are ANSI-accredited standards*
*the standards are adopted HIPAA standards*
*the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

**Comment:**
There was concern about the phrase:

*. . .level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request*

The primary problem with the current HIPAA 270/271 transaction implementation is that payers are allowed respond with a simple 'yes this person is a member' or 'no this person is not a member' and to not provide any additional information. Payers are also allowed to set up individual web sites using DDE which can have no relation to the 270/271. As a result 271responses to the 270 are often too meager to be of use to providers Or, to obtain a more robust response, the provider has to visit many individual payer web sites which is time consuming and not productive. This has created a state where there is little impetus for providers to use the 270/271 UHIN suggests that the PDPs be required under the MMA to respond with two pieces of information (1) this person is or is not a member of the PDP, and (2) if the inquiry includes the proposed prescription (in NDC), the response include whether or not this particular drug is covered under this persons PDP benefit Also, UHIN suggests that PDPs not be allowed to use DDE for this transaction It is not efficient for physicians to have to visit many web sites to obtain eligibility information. The potential offered in HIPAA for this transaction has not been realized *for providers* because of these two issues

Comment about:

*Formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer protocols established by RxHub*

*RxHub communicated to the NCVHS its intent to submit its protocols to NCPDP to be considered for adoption as an ANSI-accredited standard*

*We propose to adopt, as foundation standards in the final rule, formulary representation and medication history standards, if certain characteristics are met and there is adequate industry experience with the standards*

**Comment:**
The UHIN group was not in favor of including the *Formulary and Benefits*, and *Medication History* Standards as foundation standards for either pharmacists or physicians No one feels that there is sufficient industry experience to justify this approach

Pharmacists do occasionally receive formulary and benefits information but have not had enough experience to recommend forgoing a pilot None of the physicians in the review had ever had this type of information in an electronic form

There was a question about whether reversed/voided prescriptions (prescriptions that were written but not picked up by the patient) would be included in the Medication history Physicians suggested that there could be value in knowing that information

There was concern that, if the RxHub protocols are only now being adopted by NCPDP, how much experience with these messages *in a rigidly standardized form* has the industry truly experienced? Typically when a message has yet to be adopted by an SDO, the implementers of that message tweak it to meet their individual needs. Even when a message has been adopted, there is usually a spread of implementation that more or less conforms to the standard UHIN has no evidence that *Formulary* and *Medication History* Standards have truly been tested in a standardized and widespread fashion

Although UHIN is aware that RxHub and others have used these messages, *we do not believe there is wide-spread industry experience yet*

Comment about:

*The standards cover a range of formulary and benefit data, including information on the--formulary (for example, therapeutic classes and subclasses); formulary status (for example, drugs that the benefit plan considers to be "on formulary"); preferred alternatives (including, but not limited to restrictions that may impact whether the plan will cover a drug being considered, such as quantity limits and need for prior authorization); and copayment (that is, not just the single copayment amount for the drug being considered, but the copayments for one drug option versus another)*

**Comment:**

There were concerns about plans suggesting an alternative therapeutically appropriate drug for off-label use of prescriptions. People questioned whether a plan is in a position to suggest therapeutically appropriate formulary alternatives if they do not know the diagnosis (or the presumptive diagnosis). There is a problem with using ICD-9 or CPT codes for diagnoses in this situation. ICD-9 and CPT have largely been developed to bill, not to record detailed diagnoses or presumptive diagnoses. However, there is the issue that physicians and hospitals will mostly like be resistant to having to deal with yet another code list (like SNOMED). The group questioned how the PBM might obtain that information. For example, if the diagnosis is pneumonia, the PBM would need to know that it is pneumoccocal pneumonia vs. mycoplasmic pneumonia in order to be able to recommend a therapeutic alternative.

There is also the case when a prescription is being used as a therapeutic trial (there is only a presumptive diagnosis). Health care claims only code for diagnoses; they do not indicate if the diagnosis is tentative or firm. How would those situations be handled?

There was a question about where information on a drug would originate. Would this information come from the manufacturer? Would additional clinical trial information be included? Would it include FDA information? There is concern about the need for unbiased drug information, with the caveat that people know that the pharmaceutical manufactures fund most of the research on drugs and that, therefore, historically, much of the information on drugs has not come from an unbiased source.

Comment about:

*NCPDP is a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry.*

*Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs.*

*Third, the NCPDP SCRIPT Standard transactions we propose for adoption are recognized as the industry standard.*

**Comment:**
One of the criteria for by-passing the pilot is:

*The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner.*

Based on UHIN's experience in implementing HIPAA, UHIN recommends that HHS go further than simply adopting NCPDP Standards; **HHS should adopt specific implementations of the NCPSP Script Standard.** We recently did a detailed review of the SureScripts implementation of the NCPDP Script Standard and while what SureScripts is implementing is in compliance with the Standard, they have created their own interpretation of that Standard. For example, they often do not send elements or segments that are not required in the Standard.

This is going to create a hodge-podge of implementations of the NCPDP Standard. UHIN recommends the HHS adopt specific implementation guides of the NCPDP Standard rather than just the Standard. As we have learned from HIPAA, 'standards' which are relatively permissive get implemented in a huge variety of ways creating deep interoperability issues.

UHIN's other comment about NCPDP Script is that it appears to be designed for a mail boxing type of approach to exchanging information. Will a mail boxing approach meet the real-time requirement specified in the statute? A truly interactive system requires pushing information instantaneously between trading partners. We believe use of the GETMES will encourage many less than real-time implementations.

There is a feeling that while the parts of the NCPDP Scripts messaging standard which are being proposed for adoption as foundation standards have been tested, they have not been equally tested by all three components of the messages in the MMA rule, namely the providers, the pharmacies, and the PBMs.

It is our understanding that the parts of NCPDP Script which are being proposed as foundation standards include *New Rx, Refills, Changes, Cancellations, Formulary and Benefits,* and *Medication History.* UHIN does not feel that the *Formulary and Benefits*, and *Medication History* portions of the NCPDP Script message have been adequately implemented by all the entities who would utilize the final standard. Neither pharmacists nor physicians think that they have adequate experience with these messages to say that they know they will work. They do not think it has been applied in multiple e-prescribing programs with more than one external health care partner to an adequate degree. To our knowledge, SureScripts is the only program which has implemented even the *New Rx, Refills, Changes, Cancellations* messaging standards across many entities and it is our impression, talking from physicians and pharmacists who have participated in the SureScripts implementations that it could be argued that further work needs to be done on these standards prior to adopting them on a widespread basis.

E-Prescribing standards need to be adopted not only message-by-message but also implementer by implementer. One of the biggest mistakes of HIPAA was to mandate that everyone do all the transactions all at once. This approach created a highly chaotic implementation environment mostly to the detriment of the providers. We strongly recommend that HHS adopt a more

measured approach not only to determining the order in which these messages are implemented, but also the entities which would implement them.

There was concern raised about whether the PBMs were going to have more voice about treatment for patients The thrust of the MMA act appears to reduce costs by having input into the prescription at the point of writing the prescription. Concern was expressed that this would interfere with quality care tailored to the needs of the individual patient

It was pointed out that pharmacy and prescribers are somewhat at the mercy of their vendors in terms of what they can implement and how fast they can bring it up. It was also pointed out that pharmacists and providers would bear the brunt of the cost of bringing up these systems and yet much of the benefit would be conferred to the PDPs. There were questions about the motivation for providers and pharmacies to participate in these exchanges There is no obvious motivation written into the rule as it currently stands.

UHIN recommends that the messages in with a solid outline (——) in Figure 1 be adopted as foundation standards UHIN recommends that the messages in outlined with a broken line (– – –) in Figure1 be subject to further testing prior to adoption In particular, UHIN recommends that both the Formularies and Benefits and the Medication History message be tested in the arena of making that information available to pharmacists (upon request) Although the model is that the physician makes these inquires prior to the patient presenting to the pharmacy, there is no guarantee that the physician has actually done so; there is no way for the pharmacy to know this activity has occurred.

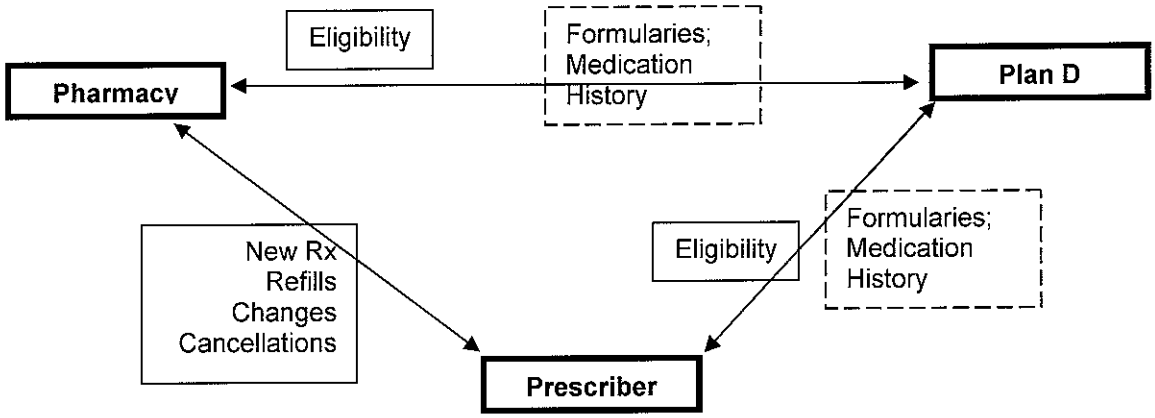


Figure 1. UHIN's recommendations for foundation standards

Comment about:

*Except not these parts of NCPDP Script:*

*the Prescription Fill Status Notification Transaction (and its three business cases*

*Prescription Fill Status Notification Transaction - Filled,*

*Prescription Fill Status Notification Transaction - Not Filled;*

*Prescription Fill Status Notification Transaction – Partial Fill)*

*These transactions will not be adopted at this time because, there is not adequate industry experience*

**Comment:**

UHIN suggests that the exchange of the Prescription Fill Status Notification Transaction be reviewed for both patient privacy and physician liability issues as well as message functionality prior to adoption Physicians are cautious about any information that might increase their liability burden. If a physician knows that a patient has not picked up a particular medication, what kind of liability does this impose? There is an impression that the liability burden varies from state to state.

Comment about:

*NCVHS Testimony.*

*most health plans/PBMs currently have e- prescribing capability either directly or by contracting with another entity. Therefore, conducting an electronic prescription drug program would not be an additional burden for those plans. Since these standards are already in use, we believe the requirement to adopt these standards constitutes a usual and customary business practice and the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).*

**Comment:**

There was agreement that the Plan Burden was estimated correctly

Comment about:

- *2003 - 3.1 billion retail prescriptions*
- *Estimate: 2006 as about 29 million Medicare beneficiaries will receive drug coverage through a Medicare Part D plan*
- *Estimate 5 and 18 percent of prescribers are conducting e-prescribing*
- *some studies have indicated increased prescriber interest*
- *Predict that MMA will accelerate adoption of e-prescribing due to heightened awareness of the benefits, the variety of devices and connections available for prescribers, and the fact that the standards are already successfully being used.*
- *Predict: the proportion of prescribers using e-prescribing will increase by about 10 percent annually over the next five years*
- *The 10 percent annual growth in prescriber participation is a rough estimate, based on our expectations of—*
- *Publicity surrounding the Medicare Prescription Drug Program;*
- *More publicity about the benefits of e-prescribing and the experience of prescribers who are participating,*
- *Increased emphasis on health information technology in general,*
- *Potential cost savings to providers using e-prescribing; and*
- *The availability of incentives for participation.*

**Comment:**
There was agreement that the anticipated 10% annual increase may be overly aggressive Also, if 5 to 18 percent of prescribers are conducting e-prescribing that mean that 95 to 82% are not UHIN feels this is a significant portion of the industry that has not had experience with e-prescribing UHIN recommends a measured approach to implementing the foundation standards.

A concern was expressed about the role of DEA in promoting or inhibiting the adoption of true electronic prescribing. Currently the DEAs lack of specification regarding a legally valid electronic signature is holding Utah back from moving aggressively forward in the area of electronic prescribing except for the use of faxes. Since the proposed rule clearly does not include faxed prescriptions, the DEA may represent a significant obstacle to the wide spread adoption of true electronic prescribing.

The group commented that the problem with the DEAs lack of action is not that Schedule II drugs constitute a significant portion of the prescriptions – they don't. Instead, the problem is that Utah, like most states, wants to develop a *single method* for all electronic prescriptions Until the DEA makes a decision regarding their version of an electronic signature this cannot happen. UHIN recommends that the Secretary encourage the DEA to make a decision and implement their decision prior to the January 2006 implementation date for the MMA foundation standards.

There are no obvious cost savings to provider for e-prescribing; e-prescribing may actually slow providers down (i e., take more time).

What is the incentive to participate in e-prescribing? Participants listed several issues that motivate providers towards adopting e-prescribing:

- Ease of use
- Saving time (go home earlier)
- Reduce staff/physician time on prescription issues
- Younger physicians are more likely to adopt (wait until older physicians retire)

Many EMRs only automate the current manual administrative process; they don't have the capability to manage clinical care. There was general consensus that an e-prescribing tool works much better when integrated into a full EMR.

There was a suggestion that HHS mandate vendors to comply with certain EMR standards.

Comment about:

*More than 8 8 million ADE occur each year in ambulatory care*

*CITL1 estimates that nationwide adoption of e-prescribing would eliminate nearly 2 1 million ADEs per year prevent nearly 1.3 million provider visits, more than 190,000 hospitalizations, and more than 136,000 life-threatening ADEs.*

*E-prescribing would promote efficient and effective use of drugs by ensuring that prescribers have up-to-date information regarding advances in drug therapies*

**Comment:**

These statements were quite controversial. There is very little known about ADEs. There isn't really any good information about the number of ADEs per year or the impact of those ADEs on the health care system. The group was somewhat skeptical about the final bullet that e-Rx would promote efficient and effective use of drugs. More studies are needed before these types of statements can be made with some credibility.

Comment about:

*Improvements, enabled by e-prescribing programs, will occur through enhanced beneficiary education, health literacy and compliance programs; improved prescription drug-related quality and disease management efforts; and ongoing improvements in the information systems that are used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers.*

**Comment:**

There was some question about the clinical impact of e-prescribing (people cited the recent study showing an increase in certain types of errors in CPOE). People were in agreement that e-prescribing would have a positive impact on problems relating to coordination between pharmacies and health providers; that is, it will be relatively easy to sell office managers on e-prescribing if it can be shown that it improves the workflow in the office. However, it still appears to be difficult to sell e-prescribing to physicians, particularly as a stand-alone tool

Comment about:

*Estimate: 100 PDP sponsors and 350 MA organizations will submit applications on an annual basis for participation in the Medicare Prescription Drug Program. Because most health plans/PBMs currently have e-prescribing capability, any additional costs associated with hardware/software connectivity would be minimal. The only expense attributable to health plans are those that would be incurred by plans/PBMs for voluntarily providing financial incentives and technical assistance to participating physicians to conduct e-prescribing. We request comments on possible costs to plans, and on steps we could take to ameliorate any unnecessary costs.*

**Comment:**

There was general consensus that this was a valid assessment of the impact on health plans/PBMs. People suggested that health plans/PBMs would bear an additional cost to pay for new transaction costs (e.g., transactions between prescriber and PBM).

Comment about:

*We request comment on our expectation, that plans will experience substantial financial benefits from e-prescribing and that the new standards will be cost-beneficial to plans. We expect many plans to provide these incentives to prescribers to offset prescribers' initial cost of installing the hardware and software, thereby encouraging the adoption of e-prescribing. We expect that this will be a transfer of costs from prescribers to health plans, and will neither increase nor decrease the overall impact of implementing an electronic prescription drug program.*

**Comment:**

There was skepticism about whether plans would incur a *substantial* financial benefit from just e-prescribing alone. The true benefits to plans are believed to come when providers utilize full EMRs with clinical data analysis capability. There was general agreement that a stand-alone e-prescribing tool doesn't bring a lot of value to physicians.

Comment about:

*Health plans have a substantial incentive to subsidize the cost of physicians' adoption of e-prescribing because the plans would share in the likely savings in health care spending through reductions in adverse events and improved compliance. We have no basis at this time for estimating the precise timing or magnitude of either gross or net savings. We request public comments and information on this topic that we can utilize when revising this analysis for the final rule*

**Comment:**

There was strong agreement with the statement that "we have no basis at this time for estimating the gross or net savings "

Comment about:

*Estimate: 5 and 18 percent of physicians and other clinicians are using e-prescribing more than 3 billion prescriptions are written annually*

*Estimate: about 203,000 physician office establishments (~88,061 physicians) The decision to adopt e-prescribing probably rests with the group rather than the individual physician.*

*Expect*

*e-prescribing to reduce prescriber costs and produce net economic benefits to prescribers, magnitude and timing of savings first will have to be demonstrated to many prescribers to induce them to make the "up front" investment in new systems An additional incentive for prescribers to e-prescribe exists, which is the improved patient care that e-prescribing brings.*

**Comment:**

There was doubt expressed about the economic benefit e-prescribing would bring to providers. Physicians are most likely to adopt e-prescribing because it saves staff time, particularly on refills and renewals. However, it doesn't seem likely to result in any economic benefit *per se*. The best implementation of e-prescribing is within the context of a full EMR. Stand-alone e-prescribing tools bring very limited value particularly since they are often focused on new prescriptions

Comment about:

*We think there are few EMR/e-prescribing vendors are currently using systems that may be in some respects incompatible with these standards We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process We request comments on whether there are some transition costs attributable to these standards and whether there are steps that we could take to mitigate those costs.*

**Comment:**

People did not agree with the comment "We expect vendors to upgrade systems at no or nominal cost as part of their normal version updating process " This is not what happened with HIPAA **Vendors usually charged substantially for these upgrades** Most e-prescribing now is via fax **People expect that there will be substantial cost associated with upgrading to the MMA messages.** In addition to the work to simply connect, there is the internal work to create and manage these messages and their associated data bases

**The connectivity will only be effective if providers can connect to a non-profit hub, a RHIO.** Without such connections providers will be forced to either connect to many pharmacies or PBMs or to work with for-profit clearinghouses which have proven to be quite expensive on the administrative side

Comment about:

*The overall costs of buying and installing systems are several factors including--*

*Changing in the business practices of providers' offices.*
*Changing record systems from paper to electronic; and*
*Training staff.*

*Expect costs to be defrayed by incentives*

*We invite comments on the nature and extent of incentives being offered to encourage prescribers to conduct e-prescribing or likely to be offered subsequent to the publishing of regulations to create an exception to the Stark law and an anti-kickback safe harbor for e-prescribing.*

*We anticipate that increased communication regarding the safety improvements and cost savings experienced with e-prescribing will encourage prescriber acceptance*

**Comment:**
The group did not see a significant cost savings for prescribers doing e-prescribing. They did envision it as a significant financial investment. The group did see a significant costs savings to pharmacies.

Regarding incentives, third party payers appear to be having mixed reactions to the suggestion that they offer incentives to prescribers for e-prescribing. Perhaps of more interest (more potential cost savings) is the Formulary and Benefits message. One provider with an internal e-prescribing tool in place has 95% formulary compliance right now. They don't' envision much ROI for the MMA rules

There were also questions regarding the impact of e-prescribing on ADEs. The group recommended that further studies be done. Very little is known about ADEs

Comment about:

*Economic benefits that accrue to prescribers that implement e-prescribing*

*A 53 percent reduction in calls from, and a 62 percent reduction in calls to, the pharmacy.*

*Time savings of one hour per nurse and 30 minutes per file clerk per day by streamlining medication management processes.*

*Decreased time spent handling prescription renewal requests.*

*Dramatic time savings that permitted reallocation of nursing and chart room staff*

*Potential reductions in malpractice insurance*

**Comment:**

The group felt that e-prescribing will have different benefits depending on whether it is part of a full EMR or a stand-alone tool. Using a stand-alone e-prescribing tool creates relatively high administrative demands as all the patient information must be entered every time the physician uses the tool to prescribe

People agreed that e-prescribing would result in decreased time in handling prescription renewal requests. However, people felt that the economic benefits e-prescribing for new prescriptions was less certain for physicians

Comment about:

*We are requesting information on these factors to help us improve our analysis for the final rule. Additional examples of administrative savings from e-prescribing, as well as costs of implementing such systems, would be particularly beneficial*

**Comment:**

The primary benefits to a physician on e-prescribing may come with increased formulary and generic prescription compliance. Many payers already have systems in place to reward physicians for this. The priority from a physicians perspective is med-med interactions, med-allergy interactions, and then formulary.

One question regarding formulary compliance is whether the plan has a formulary that is structured to increase compliance and whether it is tiered.

Comment about:

*Reported benefits:*

*Reduced time-consuming phone calls to physicians.*
*Improved accuracy and less time for refill authorizations*
*Additional time available for patient contact and services*
*Improved prescription communication between prescriber and dispenser (through, among other things, reduction in illegible handwritten paper prescriptions).*
*Improved turnaround time for refill authorizations.*

**Comment:**

Pharmacists agree that e-prescribing would result in reduced time calls to physicians, improved accuracy and less time to handle refills. However, pharmacists would not know if a physician had reviewed the current prescriptions a patient was on through the *Formulary and Benefits* message. Pharmacies do have data bases but only of the prescriptions they have filled. It is suspected that there are many people that use more than one pharmacy, primarily out of convenience

It was noted that while physicians and pharmacies bring up these systems, the refill/renewal process will actually *slow down* until the bugs are worked out and people become comfortable with the new routines

Comment about:

*Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing.*

*Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.*

*The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.*

*Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive.*

*We do request additional information on pharmacy impacts.*

**Comment:**

Point 1: The review group had problems with the statement: *Do not expect to see a material change in the volume of prescriptions written for pharmacies to fill because of e-prescribing.*

Many written prescriptions do not reach the pharmacy. The group *does* expect a material change in the volume of prescriptions that reach the pharmacy to fill. The number of prescriptions *written* may not change, but we expect that the number of prescriptions that *reach pharmacies* may increase dramatically This might pose a challenge to the pharmacies in two ways:

a It might results in an increase in prescriptions that are filled but then not picked up, which then need to be returned to stock (a very labor intensive process)

b. Patients may come to the pharmacy expecting the prescription to be ready 'immediately' because the physician has said "I've sent your prescription to the pharmacy electronically so it will be ready for you to pick up when you arrive there " In a busy pharmacy it may take over 1 hour to fill any prescriptions regardless of its source. It may be important to manage the expectations of patients

Point 2: The review group had problems with the statement: *Do not expect to see a significant economic effect from the implementation of e-prescribing in the Medicare Part D program.*

The group does expect that implementing e-prescribing will have a significant negative economic impact on pharmacies, particularly the small independent pharmacies Our experience with HIPAA has clearly demonstrated that pharmacies and physicians are usually charged by the vendor for these types of changes. Small business are often more impacted by these charges.

Point 3: The review group had problems with the statement: *The great majority of pharmacies are already highly networked for other reasons, and, therefore, assume that the marginal costs of e-prescribing are likely to be small.*

The type of networking that pharmacies currently support is pharmacy to PBM. Most e-prescribing now is via fax, not true e-prescribing The MMA rule proposes a new connection: that of pharmacy to prescriber Very few pharmacies are networked to exchange an NCPDP message with a physician; it is a completely different process than faxing prescriptions **Hence, the costs could be considerable, particularly for small independent pharmacies.**

Point 4: The review group had problems with the statement: *Since adoption is likely to be profitable, and voluntarily undertaken only where expected to be profitable, we would expect any net effects to be positive.*

Point 4 basically states that adoption will only occur where there is a good business case for it If the business case were so obvious, it would have been adopted much sooner Is it a reasonable

assumption that there will be little/no cost to pharmacies? Probably not It may be voluntary only in the sense that if you do not do it you will go out of business.

Comment about:

*Expected benefits*

*appropriate drug compliance management and Improved medication use,provide information to prevent adverse drug events*

*improve patient safety by detecting various kinds of prescribing errors, duplicate prescriptions; drug-drug, drug-allergy, drug-disease interactions, incorrect dosage strengths prescribed; problems relating to coordination between health care providers and pharmacies*

*Drive physicians to appropriate formulary choices*

**Comment:**

The group did not see how the rule would impact improved medication *use* There did not seem to be any evidence supporting this claim.

From the patient's perspective, most of the benefits are driven by the use of good *decision support* which is tied into data bases on drug-allergy, drug-drug and drug-treatment information. The messages which might most impact the patient are the Fill Status Notification messages The group has concerns about this from two perspectives:

1) Will this bring additional liability to physicians?
2) Will patients view it as a violation of privacy?

The one member of the group who has brought up an e-prescribing system noted that they can be quite effective but *physicians must first put in a lot of time tuning them.* For example, physicians may get bombarded with warnings about drug-drug, or drug-allergy interactions many of which may be irrelevant or unimportant to the particular patient. Each physician sets up rules regarding which warnings will actually be presented. This takes time and effort.

Comment about:

*Nothing in this system creates direct costs for patients*
*We believe that reductions in patient mortality and morbidity would be a substantial benefit resulting from the adoption of e-prescribing, although we are unable at this time to provide quantitative estimates*
*Patient health benefits are likely to far exceed the other categories of benefits and direct costs.*

**Comment:**

While nothing in the rule creates direct costs there will be many indirect costs to patients There will be a cost to patients to subscriber to the MMA Plan D benefits Patients who subscribe to Plan D benefits who are also covered under Medicaid will lose their Medicaid drug benefits (which may not be beneficial to the patient) The group had heard reports that other senior's plans are also going to drop their drug benefits in favor of the Medicare drug benefits; so there will be a cost to patients for participating in this system

The group did not agree with the claim that there will be a reduction in patient mortality and morbidity There are not enough metrics done at this point to make the claim believable

Comment about:

- *Expect:*
  - *Growth of e-prescribing as business potential for healthcare information technology vendors*
  - *Costs associated with e-prescribing and potential business opportunities could be allocated toward new product development.*
- *Question: Impact on entities such as*
  - *pharmaceutical and medical device manufacturers,*
  - *public health organizations,*
  - *research institutions*
  - *academic institutions*
  - *professional lay organizations*
- *We invite public comment on the impact of e-prescribing for these entities.*

**Comment:**

Public Health: the public health potential in this exchange is significant:
Prescription drugs can be used a surrogate measure of several chronic diseases
Pharmacists could send reports to the state's controlled substances data base real time.
Public health will need funding for infrastructure and training to realize this potential.

Research: Research could also benefit significantly as long as patient's privacy is adequately protected

Other entities which will be significantly impacted are rural pharmacies and rural providers, particularly hospitals Rural clinics, (e g , the rural community health centers) often act as the only acute and ambulatory care centers in the community The rule must be structured so that it does not negatively impact these critical facilities

Comment about:

*Approximately 95 percent of pharmacy firms, which account for about 51 percent of pharmacy establishments, are small business (1997 Census data)*

*Estimate that more than 29,000 pharmacy establishments would be considered small entities Includes almost all physicians in private practice*

*Expect*

*proposed rule would have an impact on a substantial number of small businesses due to the percentage of pharmacies and providers that are small businesses. distribution of costs and benefits with proportionately higher costs incurred by smaller entities than by larger entities, primarily as a result of economies of scale*

*However as many as 75 percent of pharmacies already are conducting e-prescribing and 5 to 18 percent of prescribers are using this technology.*

*This demonstrates that it is economically beneficial.*

*Predict this proposed rule would not have a significant economic impact upon a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required*

*Welcome comments on this conclusion and additional information on the small business effects of this proposed rule.*

**Comment:**
Most of the e-prescribing currently being conducted by pharmacies is fax, not true e-prescribing. **We believe there will be a significant impact on small pharmacies.** The group is not convinced that e-prescribing alone has been shown to have a positive economic benefit for physicians, particularly those in small businesses. 95-82% of physicians are NOT currently using this technology; therefore we believe the economic case has not yet been made on the physician side.

We are unsure what an Initial Regulatory Flexibility Analysis is, but if it could show that small pharmacies and providers, particularly rural pharmacies and providers would be negatively impacted then that should be documented Furthermore, those groups should be protected in the final rule if necessary.

We recommend that small pharmacies and providers who work in under served areas be given special considerations in the implementation of this rule. It is critical that these organizations continue to exist We do not believe this rule has adequately taken their special issues into account.

There was an additional concern about the Formulary and Benefits message. Rural pharmacies do not always have a particular drug on hand Physicians need to be able to says something to the effect that "I am prescribing this particular drug even though it is not on the formulary because it is the only drug available [without driving 100 miles] to this patient in this location "

Comment about:

- *Small rural hospitals*
  - *small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds*
- *Expect*
  - *Proposed rule would not affect small rural hospitals because the program will be directed at outpatient prescription drugs and not drugs provided during a hospital stay*
  - *Proposed rule would not have a significant impact on small rural hospitals because the e-prescribing provisions are both voluntary and cost-beneficial for prescribers*

**Comment:**
Most of Utah's rural hospitals (all except 1 have less than 100 beds) have swing-bed licenses and act as long-term care facilities for the local population. This rule will have an impact on these hospitals because an outpatient care service is a significant percentage of their revenue. As we stated above, the group is not convinced that e-prescribing has a positive economic impact, particularly if implemented in a stand-alone setting (i.e, not as part of a full EMR) Most of these small hospitals do not have anything approaching an EMR

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# American Psychiatric Association

1000 Wilson Boulevard
Suite 1825
Arlington, VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org

APR 13 2005



April 6, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

**RE: Medicare Program; E-Prescribing and the Prescription Drug Program CMS-0011-P**

Dear Administrator McClellan:

This is a confirmation paper version of the comments to the above-captioned proposed rule that APA submitted online to CMS yesterday, April 5, 2005, as an attached MS Word document. Enclosed are an original and two copies of the comments. Thank you.

James H. Scully Jr., M.D.
Medical Director, American Psychiatric Association

# American Psychiatric Association

1000 Wilson Boulevard
Suite 1825
Arlington, VA 22209
Telephone 703.907.7300
Fax 703.907.1085
E-mail apa@psych.org
Internet www.psych.org




April 6, 2005

Mark McClellan, M.D., Ph.D., Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

**RE: Medicare Program; E-Prescribing and the Prescription Drug Program CMS-0011-P**

Dear Administrator McClellan:

The American Psychiatric Association (APA), the national medical specialty society representing more than 35,000 psychiatric physicians, nationwide, appreciates the opportunity to submit these comments concerning the proposed rule for standards, under 42 C.F.R. Part 423, published in the Federal Register on February 4, 2005, with the title, "Medicare Program; E-Prescribing and the Prescription Drug Program."[1]

Provided there is rigorous protection of patient privacy, APA generally supports CMS' goals of enhancing patient outcomes, prescription-error reduction, and appropriate access to healthcare data. However, APA members are highly concerned about several aspects of this proposed rule on e-prescribing standards. CMS intends to accelerate physicians' adoption of e-prescribing, through proposing three standards as final foundation standards, rather than as initial standards to be pilot tested. CMS is also proposing a compliance effective date of January 1, 2006, specifically to coincide with the transition of dually eligible Medicare/Medicaid patients into Medicare Part D. APA views these as premature actions that will result in barriers to and disincentives for physicians to adopt e-prescribing.[2]

APA will detail these concerns in the ensuing comments, primarily emphasizing: 1) the impact, cost and burden on physicians electing to e-prescribe under this proposed rule; 2) negative consequences that will ensue if CMS adopts

[1] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23].

[2] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6267.

final foundation standards without pilot testing these or any other standards in 2006; 3) the adverse impact if the Secretary adopts January 1, 2006, as the effective date for compliance with e-prescribing standards; and 4) the potential for breaches in patient privacy through the technology. APA anticipates that several serious problems would arise from CMS' proposed approach to e-prescribing:

1. The three proposed final standards do not meet all the statutory criteria under the Medicare Prescription Drug, Improvement and Modernization Act (MMA) and have not yet been tested for full functionality in e-prescribing;

2. The National Committee on Vital and Health Statistics (NCVHS) recommended to CMS that it do pilot tests in 2006 for several standards functions and interoperability factors;

3. NCVHS recommended that CMS conduct pilot tests in 2006 to evaluate economic and quality-of-care impacts of automating prior authorization communications.

4. Since March 2005, after publication of the proposed rule, NCVHS made further recommendations on e-prescribing standards and privacy issues, and has an agenda to continue doing so through at least July of 2005;[3]

5. January 1, 2006, is the same effective date for the transition of dually eligible Medicare/Medicaid patients into Medicare, creating a heavy burden on physicians;

6. CMS is not confident that a National Provider Identifier (NPI) can be issued to all HIPAA "covered" dispensers and prescribers in time for a January 1, 2006, deadline;

7. January 1, 2006, does not synchronize with the initial availability in 2007 of federal matching grants for e-prescribing systems; and

8. There is only a narrow window of time to finalize and implement the statutorily mandated new Safe Harbor and new Stark II exception by January 1, 2006, to allow physicians to accept non-monetary remuneration in the form of assistance with e-prescribing systems. This is a critical shortcoming.

The degree of uncertainty with the current functional and compliance status of e-prescribing systems using the proposed standards (or others) creates a disincentive for physicians to purchase equipment and services for e-prescribing. This precisely contravenes CMS' stated goal of advancing e-prescribing within the physician community. Those who cannot easily afford e-prescribing systems, such as solo and small group practitioners, will especially be reluctant to obtain them until the support

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[3] National Committee on Vital And Health Statistics: "Final Agenda," March 3- 4, 2005. Retrieved March 30, 2005: http://ncvhs.hhs.gov/050303ag.htm

grants are available, starting January 1, 2007, and until the new Safe Harbor is clearly implemented.

Physicians will want to have solid answers about elements such as these: 1) certainty about which standards will be final; 2) whether the standards and embedding technologies will be fully integrated to allow all necessary e-prescribing functions; 3) whether the e-prescribing standards and systems will totally comply with pertinent laws; and 4) which technologies and systems will work well for various practice settings.

Until there is an established comfort level with these issues, physicians will be reluctant to commit to an e-prescribing system. Apart from a substantial initial financial outlay, they do not want to be vulnerable to costs and time-expenditures that subsequent technological changes and/or obsolescence may bring, as has been common experience with computer-based systems. They also do not want to be subject to federal sanctions for unwitting violations that non-compliant systems may engender. Also, vendors may create incentives to initiate e-prescribing through various marketing offers and other incentives that may subject physicians to violations of anti-kickback and/or Stark II laws, placing them into an untenable situation.

APA urges CMS to take these essential considerations into account, particularly as they affect psychiatrists and their patients, prior to adopting final positions on these standards-related issues.

## I. "IMPACT ANALYSIS:" Impact, Cost and Burden on Physicians to E-prescribe

### A. Scope and Method of E-prescribing

CMS assures physicians that e-prescribing is voluntary.[4] However, the proposed rule relegates the opt-out choice to the use of only paper-based transmissions of the information covered by the regulation, apart from phone calls. "Prescribers" must comply with specific e-prescribing technology standards, when they transmit, via electronic media, *any* of the types of information covered in the regulation, per 42 C.F.R. Sec. 423.160(a)(2).[5] These laws apply to every individual prescription-related data transmission.

The regulatory language encompasses a broad spectrum of patient information related to the prescription, in addition to the prescription itself. The "standards" for electronically transmitting this information are not found in ordinary off-the-shelf

[4] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[5] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273: "E-prescribing means the transmission, using electronic media, of prescription or prescription-related information between a prescriber, dispenser, pharmacy benefit manager, or health plan, either directly or through an intermediary, including an e-prescribing network." 42 C.F.R. Sec. 423.159(a).

computer software. Instead, much of the available software is proprietary and uses structured data-transmission platforms, which require certain hardware, software and web-based services. Therefore, "e-prescribing" may require a costly, integrated infrastructure.

This system typically consists of a handheld wireless device like a Blackberry for portability, a linked high-performance computer system, high-speed web access, and a web-based portal that is a hub for communications among the physician and other entities. The system will require periodic software and/or data upgrades, technicians' services to customize software and assist customers, along with service contracts. Both the physician and support staff must be trained in the system's use and become proficient with it. That requires a significant time expenditure. This is a far different, more cost-intensive enterprise, than some may envision e-prescribing to be, i.e., simply writing prescriptions and sending them with any available electronic means, such as via computerized faxes with typical off-the-shelf business software.[6]

E-prescribing information transmissions render the prescriber and dispenser "covered entities" under HIPPA, therefore such transmissions must comply with HIPAA. This is why an e-prescribing regulation defers to HIPAA's comprehensive definition of what constitutes acceptable electronic media for e-prescribing. 42 C.F.R. Sec. 423.159 states that "(e)lectronic media shall have the same meaning as this term is defined in 45 CFR 160.103."[7]

> "Electronic media means:
>
> (1) Electronic storage media including memory devices in computers (hard drives) and any removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or
>
> (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to link a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission." 45 C.F.R. Sec.106.103, at 700-701.

According to this definition, faxes that start out as paper are exempt because they are not in electronic form but faxes that originate electronically as computer files must comply with the regulation. So, if a paper prescription were scanned into a computer file, then faxed from the computer, presumably, it would not be exempt, yet the same paper prescription faxed by a fax machine would be exempt. Despite the seemingly contradictory result, this is what is legally required. Computer-generated faxes are increasingly used, so the paper-fax exception provides only a minor option. Recorded

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[7] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

voice messages, if relayed elsewhere, are also covered by this law. If electronically transmitted, any and all of this information must be transmitted in compliance with these federal laws, including HIPAA, as well as state laws and managed-care contracts. This presents physicians with yet more practical and legal burdens. HIPAA compliance is automatically mandated for physicians making electronic transmissions of such information because doing so renders them a "covered entity," under HIPAA law.[8]

Apart from prescriptions themselves, the rule covers electronic transmissions of "prescription-related information." That, too, is broadly defined:

> "Prescription-related information means information regarding eligibility for drug benefits, medication history, or related health or drug information for a Part D eligible individual enrolled in a Part D plan."[9]

It is difficult to envision precisely what type of patient information could *not* be construed as falling into the category of "prescription-related." The real choice for a physician is more complex than appears at first blush: 1) whether to adopt an e-prescribing system that complies with standards *whenever* an electronic transmission is used for any type of potentially covered patient information; or 2) use strictly non-electronic methods, except for paper-originated faxes and phone calls. Electronic transmission of many types of patient information from a physician is covered by this law, whether to a dispenser, pharmacy benefit manager or health plan, and whether done "directly or indirectly." While a psychiatrist or any other physician can still choose to use only telephone conversations, mailed paper and paper-originated (not computer-generated) faxes, other electronic transmissions for Medicare Part D patients must comply with the e-prescribing law. CMS has been advised to make a major compliance exception with regard for transmissions within an organization, such as a hospital or clinic.[10]

### B. Burden of Cost

Control of products and services in relatively few hands diminishes competition, which drives up costs for physicians. Three major for-profit companies previously teamed up on HIPAA products using these standards and are now involved in e-

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[8] HIPAA Sec. 160.103 Definitions: "*Covered entity* means: A health care provider who transmits any health information in electronic form in connection with a transaction covered by this subchapter."[8]

[9] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[10] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6265. "The e-prescribing standards that these 'closed' enterprises should use were discussed by the NCVHS. The committee recommended that organizations that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise; however, if they send prescriptions outside the organization (for example, from an HMO to a non-HMO pharmacy), then they should use the adopted standards."

prescribing. Compuware Corporation, Microsoft and Washington Publishing Company produce integrated products and services for electronic data-interchange platforms using the ASC X12N standard for claims management and HIPAA compliance. Washington Publishing Company produces a variety of technological products for physicians and other healthcare industry end-users that integrate with Microsoft products and support NCPDP and ASC X12N transactions.[11] HealthRamp and RxRite recently partnered to offer e-prescribing on the BlackBerry(R) Wireless Platform.[12]

One APA concern is that making these few standards final so soon may confer a large market share of e-prescribing business to a few major companies. It would appear that a wider range of standards would encourage market competition. Embedding these NCPDP and ASC X12N data-interchange standards into proprietary, copyrighted software and web-based services makes it harder for competitors to develop products without running afoul of other companies' copyrights. In addition, once physicians purchase an integrated e-prescribing system that includes handheld PDA devices, computers, software and web services, they are likely to be reluctant to pay more to switch system components in the near future. The early market share is likely to capture continuous users for the future. The effect of codifying specific standards into law mandating their use in e-prescribing transactions is to lock physicians into using existing standards-compatible products and services, despite their currently unknown operational problems.

CMS information on estimates of infrastructure costs for e-prescribing may be modest. CMS notes that health plans have estimated hardware and software costs for implementation of an e-prescribing system to be approximately $1500 per subscriber."[13] A cost assessment for an integrated, e-prescribing system using a handheld wireless device, such as a Blackberry, could be substantially higher. According to an article from AMA on amed.com, "(r)esearchers found that it can cost an individual physician $122,000 over five years to implement and maintain a system, although the cost can drop to $35,000 per doctor in a 50-physician practice (*Wall Street Journal*, 4/15). Also, physicians are often responsible for buying, installing and operating the systems, which can slow their workflow in the short term."[14] APA must emphasize that the majority of private-practice psychiatrists do not work within large practices, as in this example.

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[11] OnlyConnect® Retail Pharmacy Accelerator for Microsoft BizTalk Server 2002: An extension to Microsoft BizTalk Server 2002 to support National Council for Prescription Drug Programs (NCPDP) 5.1 & 1.1 transactions adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). http://www.wpc-edi.com/products/software/doctors

[12] Ramp Corporation Press Release: "HealthRamp and RxRite Partner to Offer Electronic Prescribing on the BlackBerry(R) Wireless Platform;" March 1, 2005. Retrieved March 31, 2005: http://biz.yahoo.com/prnews/050301/latu088_1.html

[13] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6270.

[14] AMA's amed.com: "E-prescribing Could Save Billions, But Adoption Lags;" April 15, 2004. Retrieved April 1, 2005: http://www.ihealthbeat.org

Instead they work solo or in small group practices that do not enjoy the ability to spread costs across a larger number. For that reason, the average psychiatrist in private practice is likely to find that purchasing an integrated e-prescribing system will be a substantial financial burden.

Here are examples of some e-prescribing system costs, not including an office computer system, software, or web-based services connectivity fees:

O2 BlackBerry 7230 Wireless Handheld: $574.95

Standards are available to members of NCPDP. Membership cost is $550/year.
Non-NCPDP members who do not wish to become members may purchase the standards, implementation guides, and/or data dictionaries at a cost of $325-$650. www.ncpdp.org

ePostRx™: "Translator" translates EDI SCRIPT messages via a web service: $2500 set up fee + an unspecified monthly payment + a per-transaction fee

ePostRx™: "Standard" $8500 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: "Professional" $16,000 flat fee + optional $300/year maintenance + one-time charge $50 per trading partner.

ePostRx™: Services and customizations are $175/hour.[15]

While the goal of required HIT standards may be to facilitate information exchange and to reduce the costs of such exchanges, the costs of acquiring standardized HIT may still be excessive for the solo practitioner. The significant costs alone are enough to discourage many practitioners from considering e-prescribing. When more potentially negative factors are added to the cost, physicians, especially psychiatrists in solo or small group practices, may determine that the disincentives to e-prescribe are overwhelming.

### C. "BACKGROUND:" New Safe Harbor and Stark II Exception for E-prescribing Assistance

A new Safe Harbor and a new Stark II exception are to be promulgated at some unspecified time in the near future.[16] These would specifically allow physicians to accept non-monetary remuneration in the form of assistance to build infrastructures for e-prescribing. CMS stated in its proposed rule that Section 1860D-4(e)(6) of the MMA requires that promulgation of a new Safe Harbor and a new Stark II exception. CMS notes that it will propose the new Stark II exception "in the near future" and that the

[15] ePostRx™ website: http://www.rxrite.com

[16] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259

office of the Inspector General (OIG) will propose a new Safe Harbor.[17] Neither had apparently been done as of the proposed rule's filing date of January 27, 2005, after the OIG had published a solicitation for new or modified Safe Harbors in the Federal Register on December 10, 2004.[18] The closing date for submission of a proposed new or modified Safe Harbor was February 8, 2005. A recent search of the Federal Register did not reveal published proposals for either a new Safe Harbor or a new Stark II exception.[19] An article from the American Medical Association (AMA)'s web publication, amednews.com, on the topic indicated that, while essential to protect physicians against prosecution for accepting assistance with e-prescribing systems, these new laws have not yet been formally proposed.[20]

It will take some time to formally propose these new rules that must then go through the potentially lengthy process toward final implementation. Yet, the proposed compliance date for e-prescribing is January 1, 2006, just nine months from now. Also, this is the same effective date as will be used for the transition of dually eligible patients from Medicaid to Medicare. This transition will affect prescribing choices and methods already, and the e-prescribing requirements will simply add to the confusion. This gap in legal protection makes psychiatrists vulnerable to prosecution, should they accept any form of value related to e-prescribing that could be construed as prohibited remuneration. Clearly, it is not feasible for them to wait until the last minute to build an infrastructure for e-prescribing. If psychiatrists accept assistance with e-prescribing systems within the next few months, it will be without the benefit of the legal protections outlined above.

Until such rules are effective, any physician dealing with Medicare patients who accepts value-in-kind such as software, hardware, web-access, training, educational materials, discounts, rebates or other assistance related to e-prescribing infrastructures may be subject to federal sanctions. Managed care entities, software, computer hardware and web-services companies will make various offers to physicians, to make their products competitive and to otherwise induce them to adopt e-prescribing practices. Some of these offers may well be construed by the OIG to constitute prohibited remuneration under anti-kickback and/or Stark II anti-referral laws. CMS mentions that, "(w)e do not know all of the various incentives being offered, but are aware that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees (as indicated above, such arrangements

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[17] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[18] OIG Notice of Intent to Develop Regulations: "42 C.F.R. Part 1001, Solicitation of New Safe Harbors and Special Fraud Alerts;" [Federal Register: December 10, 2004 (Volume 69, No. 237)]

[19] Federal Register search March 30, 2005: http://frwebgate.access.gpo.gov

[20] American Medical Association (AMA)'s web publication: amednews.com, "Physician networks offer incentives to spur EMR use: The initiatives are among the efforts being adopted to make the technology more affordable to physicians;" March 14, 2005. Retrieved March 30, 2005: http://www.ama-assn.org/amednews/2005/03/14/bisb0314.htm

must not violate Federal and State laws prohibiting kickbacks and physician self-referrals)."[21]

E-prescribing requirements should not force psychiatrists into the difficult position of choosing to either pay the entire cost of an e-prescribing system or accept assistance from external entities but risk potential federal action. While a limited amount of acceptable help in the form of federal grant money will be available to physicians in future, it will only start being funded in 2007, the year after the proposed effective date for compliance of January 1, 2006. This will not help anyone attempting to initiate e-prescribing by the effective date in 2006. [22]

### D. E-prescribing and Federal Grants

As previously noted, external assistance offered to physicians may put them at risk of falling within the definition of prohibited non-monetary remuneration. One alternative is for physicians to get matching federal grants to offset costs of e-prescribing infrastructures. But, those will only be available beginning in 2007, a full year after the proposed effective date of January 1, 2006, by which prescribers must be in full compliance with e-prescribing standards. $50,000,000 in grant money has been appropriated for fiscal year 2007. Unspecified sums are to be appropriated for 2008 and 2009, without mention of future years. Moreover, the physician applying for the grant has to agree to match at least 50% of the grant funds to cover costs for an e-prescribing program. Only one grant will be allowed per physician or per physician group.[23] Before grant money is available in 2007, many physicians may fully fund e-prescribing equipment and services purchases themselves, rather than accepting help from outside entities, to avoid any possibility of federal law sanctions.

### E. Manipulation of Physicians' Prescribing Choices

APA is concerned about the potential for using this computerized technology to manipulate physicians' prescribing choices. Especially this potential exists, since profit motivates the for-profit entities that will control the drug formularies for Medicare Part D plans. Intentional bias can be integrated into hardware and software design features to influence physicians' drug choices, as well as by "messaging" commercials or other information from drug companies, pharmacies, etc. While this may seem no less innocuous than the current practice of giving physicians free drug samples, the contrast is that this influence is not overt, obvious or even of a nature to be recognized at all. It is extremely subtle as a means of manipulation. For that reason, it is difficult to recognize it

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[21] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6268.

[22] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

[23] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Sec. 108 (MMA P.L. 108-173).

as an influence, much less actively resist it. The pharmacy industry is behind NCPDP's standards and SureScripts, Inc., which is heavily involved with e-prescribing software companies.

This industry involvement raises additional questions about incentive and bias.[24] Concerns about systems manipulation of physicians' prescribing choices were well-articulated by a panel of experts. They convened to make recommendations, published in 2004, for comparing electronic prescribing systems and selecting them to benefit patients.[25] They noted that, "(m)any developer and implementers of electronic prescribing are receiving support from third-party organizations that have incentives to influence the prescribing process."[26] Drop-down menus, order of drug choices, algorithms, graphics, visual markings, and other aspects of computerized information can subtly influence a psychiatrist's drug prescribing choices and habits. The expert panel stated that,

> "(s)ome electronic prescribing systems attempt to influence prescribers by altering the order in which medications are presented or by displaying special symbols (such as an asterisk) next to favored or disfavored options. The panel recognized that this potentially beneficial feature could also be used to create commercial advantages for third parties. To curb these potential conflicts of interest, the panel strongly recommended that the display of medication options should not be influenced by promotional considerations . . . Furthermore, the meaning of any symbols or special typefaces used to differentiate medication choices should be made clear . . ."[27]

Design and information-display bias could favor managed care companies, pharmaceutical companies or pharmacies. The psychiatrist's freedom and objectivity to determine the best choices for the patient's welfare should be retained, yet may be easily and subtly compromised in this way.

Computerized systems also offer the potential for pharmacies and pharmaceutical companies to stream commercial messages or less overt, yet influential, informational

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[24] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6266: "Second, the NCPDP SCRIPT Standard transactions proposed for adoption have been used in multiple e-prescribing programs. SureScripts, Inc. (SureScripts) selected the NCPDP SCRIPT Standard to serve as the foundation of their transaction engine software. SureScripts was founded by the National Community Pharmacists Association (NCPA) and the NACDS, which represent the interests of 55,000 chain and independent pharmacies. To date, SureScripts has signed agreements with, and tested and certified the software of, pharmacies and pharmacy technology vendors representing more than 75 percent of U.S. pharmacies. In addition, SureScripts has signed contracts with software companies who supply electronic health record and electronic prescribing applications to physician offices representing more than 50,000 current physician users."

[25] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004.

[26] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-312.

[27] Bell, DS, Marken, RS, Meili, RC, *et al*, Recommendations for Comparing Electronic Prescribing Systems: Results of an Expert Consensus Process;" Health Affairs; May 25, 2004; at W4-309.

messages, in an attempt to affect a physician's prescribing choices. CMS does not adequately address issues of design and data bias or the influence of commercial intrusions into the systems within the proposed rule. As with design bias, psychiatrists should not be subjected to streamed information that may influence their prescribing choices, in addition to diverting their time and attention from patients.

***Recommendations-Safe Harbor & Stark II:*** APA urges CMS to work with OIG to: 1) draft a new Safe Harbor to allow physicians to accept non-monetary assistance to implement their e-prescribing infrastructure; and 2) to establish an immediately effective, formal, temporary exemption from prosecution. The exemption should be effective until the effective dates of *both* the new Safe Harbor and the new Stark II exception that will take over this protective function, thereafter. APA also requests that CMS clarify when it intends to propose a new Stark II exception for e-prescribing systems.

***Recommendations-Design Bias & Prescribing Influence:*** APA strongly encourages CMS to: 1) establish clear policies prohibiting design bias in software and hardware design for e-prescribing systems; and 2) establish clear policies prohibiting streaming commercials and other superfluous information into e-prescribing systems.

## II. "BACKGROUND:" Pilot Tests for Standards are Imperative

CMS has the legal authority to pilot-test proposed standards, before they are made final. Prior to issuance of this proposed rule, CMS made its position clear, as to its promotion of e-prescribing: "(a)t the July 21, 2004 Health Information Technology Summit, we (CMS) announced our intent to accelerate the implementation of e-prescribing by proposing a first set of well-established standards for implementation by January 2006, when the Medicare Part D benefit begins."[28] The basis for proposing the adoption of several standards as final foundation standards is on the basis that there is "adequate industry experience" with them.[29]

We question whether "adequate industry experience" includes individual physicians in solo practice or those in small group practices. Therefore, we believe that standards should not be adopted as final without pilot testing of these cohorts and that more standards should be considered for pilot testing. Small scale pilot testing of e-prescribing systems with solo physicians and small group practices will help identify issues for improvement within the real-world experience of physicians. Attention must be paid to whether specialty-specific issues for psychiatrists, as well as other physicians, may well experience unique problems with these systems within their practices that pilot

[28] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6259.

[29] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6261.

tests to bring to light. Testing will also provide time to modify the technologies for maximum effectiveness, prior to widespread adoption.

CMS proposes to adopt three standards final foundation standards for e-prescribing without a pilot test. Two of these standards were developed by the National Council for Prescription Drug Programs (NCPDP), a not-for-profit Standards Development Organization, with over 1,300 members of the pharmacy-services industry.[30] Two standards have been specified by language in the new regulation, 42 C.F.R. Sec. 423.160. Therefore, these are mandated for e-prescribing transmissions: 1) NCPDP SCRIPT Standard, Version 5.0 for e-prescribing communications between prescribers and dispensers; and 2) ASC X12N 270/271 (ASC X12N), which must be used for eligibility communications between prescribers and Part D sponsors. That new regulation and the revisions to language in 42 C.F.R. Sec. 423.150 and 423.159 became effective on March 22, 2005, prior to the due date of April 5, 2005, for comments on this proposed rule on standards.[31] ASC X12N and the NCPDP Telecommunication Standard, for transmitting eligibility data between dispensers and Part D sponsors, are already adopted for and comply with HIPAA.

CMS is also considering using NCPDP standards for formulary and medication history based on the RxHub protocol; and NCPDP Provider Identification numbers for dispensers and NCPDP HCIdea, a copyrighted product for identifying prescribers.

CMS acknowledges that the three proposed final foundation standards do not meet all of the statutory criteria, under Medicare Prescription Drug, Improvement and Modernization Act (MMA).[32] In addition, they have not yet been tested for full functionality and compliance with MMA and HIPAA within integrated e-prescribing systems and by physicians within a spectrum of clinical settings.

Moreover, the National Committee on Vital and Health Statistics (NCVHS) submitted its first set of recommendations on e-prescribing standards to CMS in 2004, stating that CMS should pilot test several standards for a variety of functions.[33] In that letter to CMS, of September 2, 2004, to former HHS Secretary, Tommy Thompson, NCVHS recommended pilot tests in 2006 for:

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[30] NCPDP is accredited by the American National Standards Institute (ANSI).

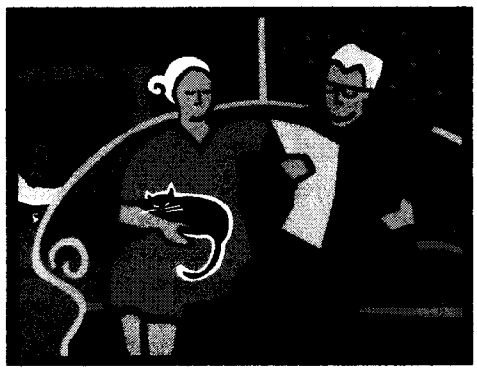
[31] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[32] CMS Proposed Rule: "Medicare Program; E-Prescribing and the Prescription Drug Program;" CMS-0011-P [Federal Register: February 4, 2005 (Volume 70, No. 23]; p. 6273.

[33] National Committee on Vital and Health Statistics (NCVHS) first set of recommendations for e-prescribing, dated September 2, 2004, to former HHS Secretary, Tommy Thompson.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
**Centers for Medicare & Medicaid Services**
**42 CFR Part 423**
**[CMS-0011-P]**
**RIN 0938-AN49**
**Medicare Program; E-Prescribing and the Prescription Drug Program**

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.
**ACTION:** Proposed rule.
**SUMMARY:** This rule proposes to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). These proposed standards would be the foundation standards or the first set of final uniform standards for an electronic prescription drug program under the MMA, and represent the first step in our incremental approach to adopting final uniform standards that are consistent with the MMA objectives of patient safety, quality of care, and efficiencies and cost savings in the delivery of care.
**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later



1/27/05

**than 5:00 p.m. on [OFR--insert 60 days after the date of publication in the Federal Register].**

**ADDRESSES:** In commenting, please refer to file code CMS-0011-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. You may submit comments in one of three ways (no duplicates, please):
1. Electronically. You may submit electronic comments to http://www.cms.hhs.gov/regulations/ecomments (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).
2. By mail. You may mail written comments (one original and two copies) to the following address ONLY:
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P,
P.O. Box 8014,
Baltimore, MD 21244-8014.

Dear1/27/2005 3:57:14 PM Secretary

How do you propose to have us use the internet and how do you propose to electronic comment if we do **NOT** understand the format. Why is getting drugs getting Harder? First of all, the eyes don't cooperate after 60, then there is the problem with the fingers. I am having a hard time with this. Hard because I have psorasis on my hands. With Posratic Arthritis in the knuckles and joints.This is documented. I have SSI for this reason.
Can You send me a copy of this information so I may participate in the discussion. Or perhaps that is not a good idea. Who WantS to listen anyway?
So Please, Lets not make things harder to save a buck. A $ is a $
Sincerely Shirley Miles 20 County Fair Trail St. Peters MO 63376

Shirley Miles

Response

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Thank you for your feedback. It has been fowarded to the appropriate parties.
Discussion Thread

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Customer - 01/27/2005 04:43 PM
This feedback is about:
http://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_adp.php?p_faqid=1.

Adobe and Long Term Care information should be part of the MainFrame of CMS and HIPAA explaining in Language we seniors understand.
Thank You for making it simpler.

I have appealed a ruling of United Health Cares Medicare Complete coverage with the insurance company in referencing the cost of perscriptions in ENBREL.....

I'm between a rock and a hard place trying to understand the terms.
Thanks
Sirley Miles
20 County Fair Trail
St. Peters MO
p.s. Our new Governor Blutt is cutting many state run programs. Therefore I need to understand better the Availabity of Government Programs under SSI and What drugs are allowed to Disabled.

Question Reference #050127-000011

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Category: Appeals Policy
Contact Information: shirleymiles@charter.net
Date Created: 01/27/2005 04:43 PM
Last Updated: 01/27/2005 04:43 PM
Status: Solved
State:

America's Health
Insurance Plans

601 Pennsylvania Avenue, NW
South Building
Suite Five Hundred
Washington, DC 20004

202.778.3200
www.ahip.net

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APR 13 2005

April 5, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Re: Notice of Proposed Rulemaking for Electronic Prescribing and the Medicare Drug Program

Dear Sir/Madam:

America's Health Insurance Plans (AHIP) is writing to offer comments regarding the Notice of Proposed Rulemaking (the "NPRM") for Electronic Prescribing and the Medicare Prescription Drug Program published in the *Federal Register* on February 4, 2005 (70 Fed. Reg. 6256).

AHIP is the national trade association representing the private sector in health care. Our nearly 1,300 member companies provide health, long-term care, dental, vision, disability, and supplemental coverage to more than 200 million Americans, including over 4.2 million Medicare Advantage enrollees.

Development of these standards, as authorized by the Medicare Modernization Act of 2003 (MMA), is an important step toward enabling electronic prescribing for the Medicare Part D program and within the health care community as a whole. AHIP supports the electronic prescribing initiative and we appreciate the opportunity to provide our recommendations to help facilitate the development of appropriate standards for electronic prescribing.

**Application of Standards Within Organizations**

***Issue:*** The standards should not be applied to electronic prescribing communications within a "closed network."

***Discussion:*** The NPRM defines "e-prescribing" as the electronic transmission of information "between a prescriber, dispenser, pharmacy benefit manager, or health plan...." (45 CFR 423.159) The NPRM applies the standards to transactions between different entities, such as an electronic eligibility transaction between a Medicare Advantage Prescription Drug Plan and a prescribing physician. The Preamble to the NPRM requests public comment about whether the standards should also apply within a specific organization (a "closed network").

***Discussion:*** The MMA provides for federal preemption of state laws or regulations: (1) that are contrary to or restrict the ability to carry out the electronic prescribing provisions of the MMA; and (2) that pertain to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions for drugs covered under Part D.

There are a variety of state laws and regulations that relate to the exchange of information by and between health care providers, health insurance plans, and pharmacy benefit managers. For example, some state laws restrict the use of electronic prescribing without express consent of a patient.[2] Other state laws require the State Board of Pharmacy to approve electronic transaction and data security standards.[3]

Health care providers, health insurance plans, and pharmacies and pharmacists will participate in electronic prescribing only if they are assured that they will not be in violation of state laws that govern their conduct. It is critical that CMS interpret the preemption language broad and consistent with the intent of the MMA so that any state law that "restricts the ability to carry out the electronic prescribing provisions of [the MMA]" will be preempted. CMS must also work to identify possible state conflicts and provide guidance regarding the impact of the electronic prescribing standards on those state laws.

***Recommendation:*** AHIP recommends that CMS broadly interpret its federal preemption authority. CMS should evaluate and specifically identify state laws and regulations that are federally preempted for electronic prescribing and issue regulations, bulletins, or other guidance explaining its preemption authority.

We appreciate the opportunity to comment on these important proposals.

Sincerely,

Diana C. Dennett
Executive Vice President

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[2] *See e.g.:* Nev. Admin Code §639.7105 and Wis. Stat. Ann. §460.11.

[3] The National Association of State Boards of Pharmacy identified a number of state requirements that could be interpreted as conflicting with federal electronic prescribing standards in testimony to the NCVHS Subcommittee on Standards and Security last year.

***Recommendation:*** AHIP encourages CMS to adopt a standards modification process that allows annual modifications to the standards. Covered entities should be permitted to continue using older versions of the standards for a period of time after those modifications are adopted.

**The National Provider Identifier**

***Issue:*** Covered entities should be permitted to use proprietary or other identifiers for health care providers prior to the implementation of the National Provider Identifier (NPI) standard.

***Discussion:*** The NPRM solicited public input about an appropriate methodology to identify health care providers. The final rule mandating a National Provider Identifier (NPI) for health care providers was published in January 2004. Although providers can begin applying for a NPI in May 2005, most covered entities are not required to begin using the national provider identifier until May 2007 ("small health plans" have until May 2008 to come into compliance with the NPI requirements).

Until the NPI compliance date is in effect, AHIP recommends that electronic prescribing standards allow the NPI as well as other identifiers to be used. Health insurance plans, health care providers, and pharmacy benefit managers are already accustomed to using a variety of identifiers including proprietary numbers, the Medicare provider number, Drug Enforcement Agency (DEA) provider numbers, the NCPDP provider identifier for pharmacies, and tax identification numbers. Some health care providers will apply for an NPI before the implementation date while other providers may need additional time to come into compliance.

***Recommendation:*** AHIP recommends that until use of the NPI is required, CMS should allow either the NPI or other identifiers to be used for electronic prescribing.

**State Law Preemption**

***Issue:*** The final rule should indicate that the standards preempt all state laws or regulations that restrict or prohibit the electronic transmission of information with respect to drugs prescribed to Medicare beneficiaries. The Department of Health and Human Services should review existing state laws and regulations and provide guidance regarding preemption.

***Recommendation:*** AHIP recommends that NCPDP be allowed to complete its review to determine whether the RxHub protocol as an appropriate standard for communicating formulary information and medication history.

**Process for Modifying the Standards**

***Issue:*** The Centers for Medicare and Medicaid Services (CMS) should work with health care community stakeholders to develop an agreed process for approving modifications to the standards through an annual interim final rulemaking process. Covered entities should be permitted a period of time to continue using older versions of the standards.

***Discussion:*** The MMA established a process for the initial development of electronic prescribing standards. The NPRM requests public comments regarding a process for modifying standards once they are initially adopted.

When evaluating a change process, we recommend CMS evaluate the "lessons learned" from the implementation of the HIPAA electronic transaction standards. HIPAA requires any modifications to those standards to undergo a lengthy review and rulemaking process before implementation. Under this process, it can take up to several years to make necessary changes to an existing standard.

It is important for electronic prescribing standards to be sufficiently flexible to meet changing business needs and advances in technology. As a result, appropriate modifications should be adopted in a timely fashion.

CMS should work with health care community stakeholders to develop an agreed process for the annual adoption of modifications to the electronic prescribing standards. The Standards Development Organization that initially developed an electronic prescribing standard, such as NCPDP, should follow its defined process for review and recommendation for modifying the standard. These modifications should be submitted directly to CMS which should release them as an interim final rule with a 60 day comment period. Once the comment period is completed, the modifications should be implemented within a reasonable time frame.

Covered entities should be given the option to continue using older versions of the standards for a period of time after the modifications are adopted and implemented to allow any necessary changes to technology and business systems.


standards for communicating eligibility and prescription or prescription-related information without pilot testing.[1] AHIP does not believe there is adequate experience with these standards and recommends pilot testing prior to final adoption. Implementation of the three standards should be delayed or made voluntary between trading partners until pilot testing is completed.

Although the standards proposed by the NPRM may be in use by some health care providers and payers, there is not widespread utilization of the standards throughout the health care community. Pilot testing will provide valuable information about the application of the standards in a variety of settings (e.g. among different types and sizes of organizations, varying transaction volumes and system capabilities, etc.). Pilot testing will allow the standards to be reviewed against the specific requirements of the Medicare Part D program.

***Recommendation:*** AHIP recommends that the three proposed electronic prescribing standards should be pilot tested before final adoption and implementation.

**Standards for Formulary Representation and Medication History**

***Issue:*** The standards for communicating formulary information and medication history should be developed through the HIPAA approved standards development organizations (SDOs).

***Discussion:*** The NPRM notes that standards are needed to permit communication of formulary information and medication history. Public comment is requested regarding the adoption of the RxHub protocol as a basis for these standards. The Preamble to the NPRM notes that the protocol has been submitted for review to the National Council for Prescription Drug Programs (NCPDP), a HIPAA approved standards development organization.

NCPDP is the appropriate organization to evaluate the proposed standards for communicating formulary information and medication history. Once NCPDP has finalized its review of RxHub or other protocols for communicating formulary information and medication history, the standards should be pilot tested and implemented.

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[1] The National Council for Prescription Drug Programs SCRIPT Standard, Version 5, Release 0, May 12 2004 (for certain messaging transactions); the American Standards Committee X12N 270/271 Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002 (for eligibility inquiries and responses between prescribers and Part D sponsors); and the National Council for Prescription Drug Programs Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999 and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) (for eligibility inquiries and responses between dispensers and Part D sponsors).


Our interpretation is that the e-prescribing definition does not include situations where various parts of an entity access health information through one or more databases within a single enterprise. Such internal communications within an organization or "closed enterprise" are not within the scope of the MMA standards because such processes are not a transmission of data requiring compliance with electronic prescribing standards. The National Committee on Vital and Health Statistics agreed with this approach by recommending that the standards not be applied to closed networks and that they only govern transactions sent outside of such organizations.

The standards are intended to establish common communication protocols for electronic transactions involving separate and distinct entities. Many entities have made significant investments in technology and processes to support transactions within their enterprise. Establishing standards for transactions within a single entity is not necessary because each entity can easily determine the most appropriate security and communication protocols to meet its unique business and operational needs.

***Recommendation:*** AHIP recommends that the standards not apply to closed networks. We suggest that CMS adopt a definition of "closed enterprise" for purposes of identifying communications within an enterprise that would be outside the scope of these rules. We propose that CMS define a closed enterprise by reference the Health Insurance Portability and Accountability Act (HIPAA) definition of "organized health care arrangement" (45 CFR 160.103).

**Pilot Testing**

***Issue:*** Pilot testing of the proposed electronic prescribing standards is critical and should be required prior to final implementation even if the standards are currently being used by some health care providers, pharmacy benefit managers or health insurance plans.

***Discussion:*** The MMA provides that the electronic prescribing standards must be pilot tested unless the Secretary determines there is "adequate industry experience" with the standards. The NPRM recommends the adoption and implementation effective January 1, 2006 of three

710 East 24th Street
Minneapolis, MN 55404-3840
www.allina.com

*Mailing Address:*
P.O. Box 1469
Minneapolis, MN 55440-1469

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March 17, 2005

MAR 23 2005

ALLINA
*Hospitals & Clinics*

Mark McClellan, MD, PhD
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
Post Office Box 8014
Baltimore, MD 21244-1850

**Re: Medicare Program: E-Prescribing and the Prescription Drug Program; Proposed Rule (Vol. 70 No.23 Federal Register, February 4, 2005)**

Dear Dr. McClellan:

On behalf of Allina Hospitals and Clinics, I appreciate the opportunity to comment on the proposed rule concerning proposed standards for an electronic prescription drug program. Allina Hospitals & Clinics is a family of hospitals, clinics and care services that believes the most valuable asset people can have is their good health. We provide a continuum of care, from disease prevention programs, to technically advanced inpatient and outpatient care, to medical transportation, pharmacy and hospice services. Allina serves communities around Minnesota and in western Wisconsin. We are in the process of implementing the electronic medical record across all of our hospitals and clinics and have a vested interest in this rule as we consider the future application of electronic prescribing.

We appreciate the step by step approach that CMS is taking in regard to e-prescribing and see pilot testing of all standards as a key requirement before any standards are to be implemented. Please do not move forward with implementation requirements until all of the kinks have been worked through via pilot testing.

We have two main areas of concern with the proposed rule, the use of the NPI and the 270/271 eligibility standards.

## I. BACKGROUND

We support the use of the National Provider Identifier (NPI) as the provider identifier in the electronic prescribing program, however we feel very strongly that the NPI should not be mandated for use until the national deadline is in place for current HIPAA transactions. Large provider groups, like Allina, are waiting for CMS to develop a method to bulk-enumerate our thousands of physicians. CMS has told us it would not even have an idea of how bulk enumeration will work until late 2005. We had been told that this would occur by September but just last Monday on a national WEDI SNIP NPI call, a CMS representative indicated that we wouldn't know anything more until year end. Without the ability to bulk enumerate until late 2005, there is no possibility that large provider groups would be ready to use the Identifiers by January 2006. This is a significant issue since the most likely groups to use e-prescribing are the large provider groups.

## II. PROVISIONS

The proposed 270/271 eligibility standard is a mandated HIPAA standard but is not yet widely used. Initial implementations have shown that there is much room for improvement on what data should be in the 271 responses. The industry must come to agreement on terms and definitions. We do not support the use of this standard until NCPDP is able to complete the guidance document and pilot testing of the standard has documented success.

Thank you for the opportunity to respond to these proposed standards. We look forward to the next stage in the development of a solid foundation for electronic transactions. Please feel free to contact me if you have any questions regarding our comments. I can be reached at 612-775-9744.

Sincerely,

Nancy G. Payne

Nancy G. Payne, RN, MA
Director Regulatory Affairs

Gary Levine
Senior Director
Business Planning & Development

Medco Health Solutions, Inc.
100 Parsons Pond Drive
Franklin Lakes, NJ 07417

tel 201 269 6642
fax 201 269 2935
www.medco.com

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medco

April 4, 2005

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-0011-P
P.O. Box 8014
Baltimore, MD 21244-8014

Dear Madams/Sirs:

Medco Health Solutions, the nation's largest pharmacy benefit manager appreciates the opportunity to submit comments in response to the Department of Health and Human Services' Center for Medicare and Medicaid Services (CMS) Notice of Proposed Rulemaking (NPRM) on February 4, 2005. The proposed rule, at 70 *Fed. Reg.* 6256-6274, is intended to be based on section 1860D-4(3) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA).

In our comment letter we wish to make the following major points with respect to preemption of state laws and regulations that conflict with e-prescribing and the MMA:

**BACKGROUND**

**"A2. Statutory Basis: State Preemption"**

**1. The Scope of Preemption in the Final Rule Should be Broadened so that the Standards Issued Under the Rule Facilitate Rather than Impede Nationwide e-Prescribing**

The narrow scope of the preemption language proposed in the NPRM would make e-prescribing more difficult once a final rule is adopted. In its current form, the proposed rule seems to simply add one more narrow set of rules for e-prescribing standards on top of the confusing web of state legal restrictions. The current – and proposed – landscape greatly impedes the development of a nationwide e-prescribing standard.

Medco firmly believes that the standards of the final rule should be written to preempt any state law that is contrary to the standards or restricts the ability to carry out the MMA. Further, the final rule should be written so that federal preemption pertains to the electronic transmission of any information relating to medication history, eligibility, benefits, and prescriptions with respect to covered Part D drugs. Only then can the regulations facilitate the progress of e-prescribing within the timeframe envisioned in the MMA.

The NPRM itself recognizes that e-prescribing will bring many benefits to the American healthcare system. The U.S. healthcare delivery system currently is complex, inefficient, and highly fragmented. The Institute of Medicine concluded that the application of health information technology can improve both the efficiency and the quality of healthcare costs.[1]

The application of such technology to prescriptions is an especially important source of potential improvements. Patient health will benefit from a reduction in medication errors and adverse drug events, which, according to the Institute of Medicine, account for more than 770,000 injuries or deaths each year in hospitals. E-prescribing can reduce the incidence of medication errors by, among other things, helping to prevent illegible scripts and by providing prescriber access at the point of care information about potentially dangerous drug interactions. One study cited by the Institute for Safe Medication Practices (ISMP) found a 55% reduction in medication errors after electronic prescribing was instituted.[2]

E-prescribing also can help providers monitor whether the patient actually receives the prescribed medicine. According to one estimate, about one-third of written prescriptions may not be filled nor delivered to patients. Noncompliance with medication regimens is associated with over 125,000 deaths annually in the United States.[3] Finally, e-prescribing can reduce the burdens and costs on physicians. The NPRM cites estimates that almost 30 percent of prescriptions require pharmacy callbacks that result in 900 million prescription-related telephone calls placed annually. (NRPM, p. 6260). Electronic interactions through e-prescribing can greatly reduce the number and extent of such interruptions for prescribers. As the NRPM concludes (p. 6260), "...even small improvements in quality that are attributed to e-prescribing may translate into significant health benefits."

Due to these acknowledged benefits, the MMA has created a comprehensive electronic prescription program for payors, providers and pharmacies that manage benefits and prescribe and dispense covered Part D drugs. Congress did not expressly require the adoption of e-prescribing by Prescription Drug Plans (PDPs), Medicare Advantage plans that offer a pharmacy benefit program (MA-PDs) or providers, but provided that HHS would promulgate uniform standards for those that do adopt the e-prescribing program. However, in the NRPM HHS has mandated that PDPs and MA-PDs shall implement electronic prescribing programs and that the programs utilizing the foundation standards should be available on January 1, 2006. While participation by providers and pharmacies is voluntary, some will utilize e-prescribing because of contractual requirements of a health benefit plan in which they participate.

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[1] Institute of Medicine, To Err Is Human: Building a Safer Health System (Washington, DC: November 1999) and Crossing the Quality Chasm: A New Health System for the 21st Century (Washington, D.C.: March 2001).

[2] Institute for Safe Medication Practices (ISMP), white paper, "A Call to Action: Eliminate Handwritten Prescriptions Within 3 Years!" 2000.

[3] National Association of Chain Drug Stores (NACDS), "The Chain Pharmacy Industry Profile 2001."

The MMA requires that e-prescribing include real-time electronic delivery of certain specific information on eligibility, benefits, drug interactions, warnings, dosage adjustments, medication history, and the availability of generic substitutes to providers and pharmacists. This information must be provided in a secure format that complies with health privacy regulations. The system also must permit the electronic exchange of FDA drug labeling and listing information. E-prescribing systems are intended to provide a near-term foundation for the continuing implementation of systems for electronic medical records.

The MMA contains a statutory requirement for HHS to issue regulations that provide standards for e-prescribing that pertain to electronic prescribing programs. It sets an ambitious schedule for issuance of the e-prescribing standards and their implementation.

Three factors are critical to the development of a nationwide e-prescription capability. First, participation – especially by physicians – is voluntary. Moreover, the adoption of e-prescribing systems involves externalities; the benefits also accrue to other parties besides the physician or pharmacy that adopts the system. This means that the parties who benefit from e-prescribing must have flexibility to compensate one another and create incentives for prescribers and pharmacies to adopt new e-prescribing systems. The MMA recognizes this and authorizes the Secretary of HHS to provide incentive payments to physicians to help defray their costs. As discussed below, the MMA also provides for a safe harbor from federal anti-kickback laws and an exemption from federal limitations on physician referrals (the "Stark law") so that participants in the e-prescribing network can compensate one another for joining.

The second critical factor in e-prescribing is scale. In other words, similar to the expansion of the telephone or Internet, the e-prescribing system will offer increasing benefits that multiply according to the number of participants in the system. To achieve scale requires that as many appropriate parties as possible – physicians, pharmacies, hospitals, pharmacy plans, pharmacy benefit managers, etc. – be included in the expanding network. Scale also requires a nationwide system that is accessible by parties who are located in all parts of the country. Again, the MMA recognizes this and requires HHS to issue regulations to create national uniform standards that preempt any state law or regulation. This preemption would include information that pertains to the electronic transmission of a medication history, information on eligibility, benefits, and prescriptions for covered Part D drugs and that is contrary to federal standards or restricts the ability to carry out the electronic prescribing program for Part D medications.

Tthe MMA does not require HHS to issue regulations defining the scope of that preemption. Rather, the standards themselves automatically preempt conflicting or burdensome state laws and regulations. The purpose of any HHS action to define the scope of preemption in regulations should be to make the process of implementing the standards as smooth as possible to facilitate and encourage their adoption so that HHS can meet the tight deadlines for e-prescribing that the MMA sets.

The third necessary element in e-prescribing is interoperability. The history of electronic technology development is littered with multiple systems that could not talk to one another. Today, even companies that produce potentially proprietary information technology systems recognize the benefits of interoperability.[4] This relates to scale. With interoperability, the participants in an information network reap substantially greater benefits than if that network is divided into smaller fiefdoms.

The MMA addresses the issue of interoperability in multiple ways.[5] To institute nationwide e-prescribing, the MMA requires the Secretary of HHS, with recommendations of the National Center for Vital Health Statistics (NCVHS), based on consultations with a range of industry and government stakeholders, to adopt, recognize, or modify uniform standards for the e-prescribing program. The Secretary must develop initial standards by September 1, 2005 and must pilot test them beginning in 2006 unless the Secretary determines that the initial standards reflect "adequate industry experience." Final standards must be in place by April 1, 2009.

To assure interoperability, and preclude the division of the country into separate areas that might lack access to the common e-prescribing network, the MMA provides that the standards will preempt state laws and regulations that conflict or interfere with e-prescribing programs. Without preemption, as will be discussed below, e-prescribing would lack both the scale and interoperability that are needed for a successful nationwide system.

## 2. E-Prescribing Can Become a Practical Reality Within the Timeframe Mandated by the MMA Only if HHS Issues Standards That Effectively Preempt Conflicting State Laws

There is a consistent and growing body of knowledge about the factors that, until now, have impeded the emergence of e-prescribing on a nationwide basis. One major factor is the reluctance of physicians to adopt new e-prescribing technologies.[6] The other factor is

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[4] See, e.g., Steve Lohr, "High-Tech Alliance on Base for a Digital Health Network," *New York Times*, January 26, 2005. ("Eight of the nation's largest technology companies, including IBM, Microsoft and Oracle, have agreed to embrace open, nonproprietary technology standards as the software building blocks for a national health information network.")

[5] In addition to creating the Electronic Prescription Drug Program, the MMA provides for a number of initiatives that relate to electronic or technology-enabled programs to reduce costs and improve quality of care. These initiatives include: a) grants to physicians to implement electronic prescription drug programs (Section 101); b) an IOM Study on Safety and Quality to provide a blueprint for system-wide change (Section 107); c) an IOM Study on Performance Measures to identify information technology requirements in aligning performance to payment for service (Section 238); d) an extension of telemedicine demonstrations and doubling the available authorized funding for patient safety improvements using information technology (Section 417), e); a 3 year CMS pay-for-performance demonstration program using health care information technology at 4 separate sites (Section 649); f) establishment of a new Council for Technology and Innovation within CMS for oversight of technology enhancements (Section 942), g) establishment of a new Commission on Systemic Interoperability to focus on standards development acceleration and adoption (Section 1012); and h) creation of a health care infrastructure loan program including $200 million in grant funding over 54 months for loans to providers to implement technology (Section 1016).

[6] "In health care, the average investment in information technology computer hardware, software, and services is only about $ 3,000 annually for each worker, compared with $ 7,000 a worker on average for private industry and nearly $ 15,000 a worker in banking....But health care remains a fragmented industry, with much of the care still

the patchwork of overlapping and sometimes conflicting state laws, and regulations issued pursuant to those laws, that make e-prescribing difficult if not impossible.

The e-prescribing regulations that HHS will issue to implement the MMA have the potential to help resolve both of these interrelated issues. The NRPM, however, takes a cautious approach that should be modified in the final regulations if they are to help rather than hinder the expansion of an e-prescribing network.

One way to overcome physician inertia is to provide incentives for them to adopt the new electronic technologies needed for e-prescribing. This is a mandate on HHS as a part of President Bush's Executive Order on Incentives for the Use of Health Information Technology, E.O. 13335, issued April 27, 2004.

While plans or pharmacy benefit managers may have an opportunity to lower a physician's capital requirements to provide adopt electronic prescribing capabilities through incentives, as the NPRM also points out, a major impediment to the provision of these needed incentives is the existence of federal and state laws prohibiting kickbacks and physician self-referrals. The NPRM states that HHS will address these impediments by issuing a proposed rule to create an exception under Section 1877 of the Act (the "Stark law") for incentives relating to e-prescribing and that the department's Inspector General is considering how best to establish a safe harbor under the federal Anti-Kickback statute.

The Government Accountability Office points out that state law is prevalent in this field: "Many states have laws analogous to the federal self-referral and anti-kickback laws, some of which are stricter or have fewer exceptions, or both."[7] However, the proposed rule fails to preempt or otherwise address these conflicting and burdensome state laws.

The second major impediment to the spread of e-prescribing is the patchwork of laws and regulations in the 50 states and the District of Columbia. Section 1860D-4(e) of the MMA addresses this impediment in clear language. It directs HHS to issue standards that preempt any state law that pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs and that is contrary to the standards or restricts the ability to carry out the MMA.

However, the NPRM does not adopt the statutory requirement. It would limit (p. 6257) any preemption to prescriptions with respect to covered Part D drugs *prescribed for Part D eligible individuals*. This approach unreasonably narrows the scope of the MMA with respect to e-prescribing. E-prescription depends on the ability of prescribers and other members of e-prescription networks to conform their e-prescribing systems to a single set

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provided by physicians in small practices." Steve Lohr, "Health Industry Under Pressure to Computerize," *New York Times*, February 19, 2005.

[7] Government Accountability Office, *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, GAO-04-991R, August 13, 2004, p. 47.

of standards that apply across the nation. The public is not well served by policies that permit conflicting state laws and regulations to preclude a nationwide e-prescribing system.

Virtually all payors' and providers' patient bases have multiple and different benefit programs. Applying standards only to Part D beneficiaries for covered Part D drugs creates multiple problems. In states that prohibit e-prescribing, for example, a prescriber would need to create a system exclusively for prescriptions for Part D individuals, while continuing to prescribe by hand for all other prescriptions for those states.[8] Also, in cases where Part D coverage might be denied for a patient at a time after the physician has written a prescription for an eligible Part D drug, the physician then would face the prospect of being found in violation of a state law that otherwise would have been preempted. The Pharmacy that dispensed the prescription would also find itself at risk. Expanding preemption to Part D patients rather than covered Part D drugs makes more sense.

Besides states that prohibit e-prescribing outright, the major problem that exists involves the myriad of often small differences between state laws or regulations that can prevent e-prescribing from achieving the needed scale and degree of coverage to be attractive to many prescribers. While any one standard may be beneficial, a multiplicity of requirements makes uniform coverage difficult if not unworkable. Consider the following state requirements presented in testimony of the National Association of Boards of Pharmacy (NABP) to the NCVHS Subcommittee on Standards and Security[9]:

- The states of Nevada and Ohio require that the state Board of Pharmacy approve the e-prescribing system (NABP, pp. 7 and 9).
- The state of Washington requires such Board approval every three years (NABP, p. 11).
- In Maryland, any "commercial intermediary must guarantee the confidentiality and security of transmission process in a manner approved by the Board" (NABP, p. 5).
- The states have varying requirements for prescription forms. For example, the state of Alabama allows electronic transmission but requires that the prescriber must write "Brand Medically Necessary" whenever a specific brand must be dispensed (NAPB, p. 1).
- The states have a variety of requirements concerning whether a prescriber may provide the electronic prescription to a pharmacy through an intermediary and the nature of permitted intermediaries.
- The states have a variety of electronic signature requirements.

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[8] The testimony of the National Association of Boards of Pharmacy to the NCVHS Subcommittee on Standards and Security, July 28, 2004, identifies South Carolina and South Dakota as states that do not allow electronic transmission of prescriptions. See p. 10.

[9] *Ibid.* at the pages indicated.

Such requirements are serious obstacles to the expansion of e-prescribing. For example, the requirement for Board approval of the system creates the risk that the Board of Pharmacy of a single state might invalidate a system in which the e-prescriber has made a significant investment. It also risks freezing the level of technology in cases where a Board publishes an approved list of e-prescribing systems that is only infrequently updated.

Depending on the state, some of the conflicting requirements are set by law while others appear in regulations. Indeed, state regulations can be more troublesome than state statutes because (1) they can often be proposed and adopted with little public notice (as compared to state statutes) and (2) they can be difficult for a party to obtain, compared to statutes that the states often codify.

Whether embodied in state laws or regulations, state requirements vary in ways that impede the development and implementation of nationwide standards. For example, electronic signature requirements differ among the states, as do requirements about whether the physician may transmit the prescription to the pharmacy through an intermediary. A major potential impediment for prescribers is the variation in prescription forms of each state; to assure interoperability, prescribers need to have access to a standard prescription form that applies regardless of the state where a patient may decide to obtain his or her prescription medication. This is needed, for example, to accommodate the needs of elderly patients who may move from their homes to warmer climates in the winter.

The specific and varying state requirements come on top of other state laws and regulations, such as the anti-kickback and physician self-referral laws noted above, that do not expressly reference e-prescribing despite posing significant obstacles to the implementation of nationwide electronic provision of prescription services. .

The problem with variable and changing state requirements is that prescribers face significant sanctions if they fail to comply with each of them. This creates enough uncertainty that prescribers are unlikely to actively implement an e-prescribing system even if they were able to achieve technical compliance with each state's requirement at a particular time. At a minimum, there are significant incentives for providers of electronic delivery of prescription drug services to skip service to states where the requirements are onerous, unclear, or at variance with requirements of a number of other states. The Government Accountability Office observes:

> "[H]ealth care providers are uncertain about what would constitute violations of those laws or create a risk of litigation. To the extent that there are uncertainties and ambiguity in predicting legal consequences, health care providers are reluctant to take action and make significant investments in health IT."[10]

[10] *HHS's Efforts to Promote Health Information Technology and Legal Barriers to its Adoption*, p. 44.

The MMA sets an ambitious timetable for the enactment by HHS of the standards needed to make nationwide e-prescribing a reality. If HHS is to meet this timetable, then the rules that promulgate the needed framework for e-prescribing standards, including the final rule for the standards in the current rulemaking, should adopt a more complete reading of the MMA's statutory mandate to preempt state laws.

**3. Congress Expressly Preempted the Field of Electronic Prescribing**

To properly assess the intent of Congress, not only the language of the statute but also the full scope of the MMA and the Part D benefit must be considered. First, Congress recognized that electronic prescribing was an important step in establishing an electronic infrastructure for the U.S. health care system. It is clear that Congress mandated these broader initiatives in recognition of the multiple barriers to the objective of creating such an infrastructure and not just in implementing e-prescribing programs. See footnote 5, *supra*.

Second, Congress defined the Part D benefit to include far more than the cost of the drugs. As a component of the Part D benefit, beneficiaries are entitled to the following: (1) access to drug specific information on covered Part D drugs, including through pharmacy networks, how a PDP formulary functions and how a beneficiary can obtain access to information about access to Part D covered drugs and pharmacy networks, formularies and beneficiary cost-sharing requirements, (2) mechanisms for responding to beneficiary questions and providing information via the Internet about changes to formularies and explanations of benefits, (3) access to pharmacies, (4) meeting requirements for development of formularies that must include products in every therapeutic category and periodic evaluations of treatment protocols and procedures, and (5) cost and utilization management, quality assurance and medication therapy management programs. The medication therapy management programs are targeted to beneficiaries with multiple conditions, taking multiple drugs and likely to exceed drug spending targets set by HHS. The elements of the program include patient compliance regimens, (refill reminders, special packaging and other programs and means), and coordination with chronic care improvement programs. By definition, the full scope of the Part D benefit goes far beyond the acts of paying for Part D drugs and includes a broad set of entities and transactions. The preemption provisions provide in § 1860D-4(e)(5):

> The standards promulgated under this subsection shall supersede any State law or regulation that--(A) is contrary to the standards or restricts the ability to carry out this part; and (B) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered part D drugs under this part.

The meaning of the term "standards' is important. As set forth above, Congress meant that a comprehensive drug benefit and attendant health care components would be greatly enhanced by an electronic prescribing program. As such, the statutory definition and scope of the term "standards" is very broad.

**"E. Current E-Prescribing Environment"**

Standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. We recommend that the final standards be flexible and scalable in an effort to encourage adoption from small to large health care organizations and low to high-volume prescribing physician specialties. Electronic prescribing standards must allow for basic stand alone electronic prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency, and integration with existing management software and electronic medical record systems when making an investment.

Medco recommends that HHS encourage DEA to publish its long awaited decision on electronic signatures, and that it be applicable to more than just highly controlled substances such that prescribers and dispensers do not have to implement multiple electronic prescribing requirements, but rather a single effective and practical method which will encourage the full benefits of e-prescribing.

**"F. Evolution and Implementation of an Electronic Prescription Drug Program"**

**Process for evolution of standards:**

Medco believes that a private sector approach through ANSI accredited SDOs for standards development for e-prescribing is needed, with the federal government participating in the standards development process. We recommend that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to what has been experienced with the HIPAA administrative transactions standards

In addition, Medco recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards have an open updating process and any interested party should be eligible to submit proposals for additions and modifications to the standards. In addition, we suggest a responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders maintain the vocabularies. Medco does not believe that it necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

**"G. Electronic Prescription Drug Program"**

**Versioning of standards**

Medco recommends that:

- HHS adopt minimal version levels of the standards;
- HHS depend on existing SDO enhancement processes for newer versions;
- Health care organizations be permitted to use newer versions provided there is backward compatibility. Medco recommends NCVHS periodically conduct hearings to determine when new minimum version levels should be adopted. If NCVHS considers the proposed changes to be substantive (as described in Federal Register Page 6267) HHS would issue a NPRM within 90 days. If the change is not substantive, it would waive notice and comment.

Medco is concerned about any possible divergence between HIPAA standard transactions and the same transactions, such as the 270/271 eligibility inquiry, that are employed in this NPRM. Therefore, we recommend that procedures be designed to meet the changing needs of HIPAA and e-Prescribing, but that such modifications to standards do not result in multiple standards.

**Use of National Provider Identifier**

Medco believes standard identifiers are extremely important for these transactions. It makes the following recommendations:

- That the NPI be the primary identifier for prescribers and dispensers.

- That current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

- That the required date for use of NPI in transactions in this NPRM must not be sooner than the required date for use of NPI in HIPAA transactions. Before NPI can be mandated there must be sufficient time for batch enumeration and data dissemination to become available. We believe that the NPRM date of January 2006 is premature because of non-availability of these NPI system capabilities.

**Formulary and Medication History Standards**

Medco recommends that the formulary, benefit and medication history messaging standards currently being developed be pilot tested before HHS releases final standards. Vendors should be factored into the regulation process and be encouraged to bring products to market that assist physicians to comply with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered as pharmacies

and pharmacy benefit managers must have systems operational to test prescriptions that comply with new standards.

Medco urges HHS to make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-governmental differences from across the Federal government in the Addendum to the Electronic Transactions and Code Sets rule. The additional time it took to resolve these differences left inadequate time for the various vendors to work with their customers (the provider and payer communities) to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long, and not conducive to industry usage.

**Medication history standards**

Medco recommends that private sector development and maintenance and modifications to standards not be hindered by extensive rule making processes.

Medco is concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the privacy rule is powerful privacy protection, the control mechanisms necessary to know what is "minimally necessary" and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

Current models for retrieving prescription and medical history are developing and are incomplete. For example, patients often use multiple pharmacies thereby rendering prescription records at any one physical location incomplete. Further to the point diagnostic reasons for a prescription may not always be accurate

## PROVISIONS OF THE PROPOSED REGULATION

### "B. Proposed Definitions"

Medco recommends that the definitions provided in FR 6265 be written more generically without reference to Part D. E-Prescribing regulations and voluntary efforts based on regulations are likely to evolve to Medicaid and other plans, therefore definitions should not be restricted to the single initial plan.

physician's intended use is an efficient mechanism to determine whether the expense is eligible or ineligible for coverage under the plan.

- Same Drug; Multiple Uses: It is common for one drug to have multiple uses. For each condition, where use is FDA approved or recommended by an authoritative group, the recommended initial dose and the duration of therapy can vary significantly depending on the needs of each patient and on their specific conditions. Without knowing the diagnosis, it is impossible to provide reliable information on dosage adjustments and other important warnings and cautions. Examples include:

  Prilosec: Prilosec has eight approved indications. The recommended dose of Prilosec for an active duodenal ulcer is 20 mg once a day for a period of 4 weeks. Some patients may need an additional 4 weeks. However, if the patient has Zolinger-Ellison Syndrome, the recommended dose is 60 mg once a day, with continuous treatment.

  Coreg: The appropriate dose when used for congestive heart failure would be 3.125 mg twice a day. But if Coreg is used for hypertension, the recommended dose is twice as high.

- Different Drugs, Different Uses, Confusing Names: Sometimes medication is selected in error because the names are similar with slightly different spelling or pronunciation. Diagnosis codes allows prescribers, dispensing pharmacists, Pharmacy Benefit Managers to check the diagnosis code against the dosing specific to the patient's condition. Examples of drugs that have been mixed up include the following:
  Imferon (an iron replacement) and Interferon (for cancer therapy)
  Xanax (for anxiety) and Zantac (for ulcers)
  Celebrex (for arthritis) and Celexa (for depression)
  Quinine (for nocturnal leg cramps and treatment of malaria) and quinidine (for abnormal heart rhythms).

- Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the drug prescribed is required by the statute. Without knowing the diagnosis, accurate information regarding lower cost or therapeutically appropriate alternatives cannot be provided in many cases. In fact, too often prescriptions are written when there is no evidence that the drug is either appropriate or effective. Marketing efforts coupled with new products and more approved indications for an existing product have contributed to prescribing patterns that fall outside reasonable guidelines. There are many possible examples, including:

sector in funding development of analysis and educational documentation making that helps providers understand the economic benefits for e-Prescribing.

## PROVISIONS OF THE PROPOSED REGULATION

### Other

We propose adding the requirement of a Diagnosis on the prescription to the e-prescribing rules. Requiring a diagnosis on the prescription:

- Supports many of the Medicare electronic prescription drug program requirements and in some cases is necessary to achieve the program requirement.
- Complies with HIPPA.
- Supports and is consistent with MMA cost control and quality improvement requirements.

### Diagnosis codes support other electronic prescription drug program requirements

The Act requires an electronic prescription drug program to provide for the electronic transmittal of certain information to the prescribing health care professional and to the dispensing pharmacy and pharmacist. The following statute-required information would be greatly facilitated if the diagnosis code was on the prescription:

- Information on eligibility and benefits (including drugs included in the applicable formulary, any tiered formulary structure, and any requirements for prior authorization) is required by the statute. Diagnosis codes can help determine eligibility for prescription plan coverage. Some prescription drugs have multiple uses, some of which are eligible for coverage under Medicare while others are not. Without knowing the diagnosis, plans and pharmacy benefit programs have limited ability to efficiently determine whether the plan's coverage criteria have been met. Examples of how inclusion of the diagnosis on the script facilitates coverage decisions include:

  Zofran or any anti-nausea or anti-vomiting drug is covered by Medicare under Parts A and B by most plans when used for "medical care and treatment", such as following chemotherapy or for the prevention of post-operative nausea and vomiting. A use usually not eligible for plan coverage is nausea associated with seasickness for an upcoming summer cruise or fishing trip.

  Botox has approved uses for several conditions with doses substantially higher for cervical dystonia than for other medical uses. However, Botox Cosmetic for wrinkles is seldom an eligible plan expense. Since Botox is identical to Botox Cosmetic, it could be used as a cosmetic treatment. Having the diagnosis on the prescription as the representation of the

**"E - Proposed Standards - Eligibility**

**Adopt ASC X12N 270/271 where Appropriate.** For eligibility inquiry and response, the HIPAA Transactions and Code Sets rule adopts the NCPDP Telecommunication Standard for pharmacy inquiry and the ASC X12N 270/271 for physician and other provider inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA.

**Plans should respond with more than "yes" or "no".** In the current HIPAA 270/271 eligibility transaction, a health plan may either provide detailed benefit information or simply respond "Yes, this person has coverage, or No, this person does not have coverage". Physicians need more detail than yes/no and they need the information in a more consistent format. At a minimum, plans should respond whether the patient is covered, and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. Medco recommends that the requirement for better response information be strengthened

**Regulatory Impact Analysis**

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2012 with a slightly lesser cut in 2013. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40% less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of improved efficiency, patient safety and health care quality through electronic prescribing.

Medco believes that e-prescribing offers significant financial and other benefit potential to providers. But that case may not appear compelling to many providers in the financial environment between now and 2014. We recommend that CMS partner with the private

The patient "asked for it" or "expected it". Antibiotics are often cited as examples.

The medication was selected in error.

The medication was selected as an experimental approach without evidence. Neurontin is an example where aggressive marketing efforts resulted in 78% non-FDA approved use of the drug. There are reports that off-label marketing was often supported with nothing but anecdotal evidence often sponsored or created by the drug company, with little or no hard data. For some conditions they also promoted dosages that exceeded FDA-approved guidelines.

The prescribing physician is involved in research that has not yet been published, but benefits to the patient are quantifiable and substantial. Best practice begins somewhere – and when substantiated as effective and appropriate, sharing with others sooner is to the benefit of all.

- Information that relates to the medical history concerning the individual and related to a covered Part D drug being prescribed or dispensed, upon request of the professional or pharmacist involved is required by the statute. The statue recognizes the importance of the medical history and intends to propose standards for communicating medical history at a future date. Clearly, if medical history is important, current medical status (diagnosis) should be an even higher priority.

**Diagnosis Code Complies with HIPPA**

The statute requires that information shall only be disclosed if the disclosure of such information is permitted under the Federal regulations (concerning the privacy of individually identifiable health information) under the Health Insurance Portability and Accountability Act of 1996. The department of Health and Human Services has confirmed that requiring a diagnosis or diagnosis code on a prescription requires no separate special authorization because it falls within the treatment, payment and healthcare operations category of the privacy rule.

However, there may be specific circumstances under which diagnosis is deemed inappropriate by the prescriber or patient, e.g., when doing so might compromise patient adherence to therapy or confidentiality. Therefore we suggest when it may be inappropriate to include the diagnosis or indication on the prescription, this information can be communicated to the pharmacy concurrent with the prescription being placed (verbally or written separately), or after the drug is dispensed. A concurrent transmission is preferred, as it prevents delay in dispensing and counseling, or the need to address dispensing or counseling errors after the fact.

**Diagnosis Codes Supports MMA Objectives**

Diagnosis codes supports and facilitates the Medicare Modernization Act's cost control and quality improvement requirements. Specifically the MMA regulations state:

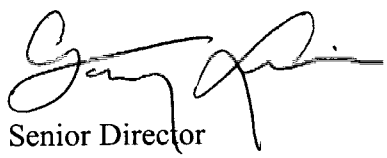
- Each plan sponsor must have established a drug utilization management program, a quality assurance program, a Medication Therapy Management Program and a program to control fraud, abuse and waste.

- A reasonable and appropriate drug utilization management program must include incentives to reduce costs when medically appropriate; maintain policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, and provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

- A quality assurance program must include measures and systems to reduce medication errors and adverse drug interactions and improve medication use.

Knowing the diagnosis is key to any utilization management program. Without the diagnosis, presumptions and guess work replace fact-based decision making. In many cases, utilization management programs spend time and money to confirm a diagnosis so that utilization review can be performed. Diagnosis supports and facilitates the MMA objectives and it can reduce the need for prior authorization and other utilization management programs. The diagnosis would illustrate the prescribing physician's intended use and thereby eliminate or reduce the need to contact the physician. An efficient, fact-based process should translate to easier approvals (or denials) of prescription plan coverage with savings in the tens of millions to Medicare and Rx drug benefit plan sponsors.

Gary S. Levine



Senior Director
Business Planning & Development

**BlueCross BlueShield Association**

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

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April 5, 2005

The Honorable Mark McClellan, MD, Ph.D.
Administrator
The Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Via Electronic Mail

Attention: **CMS-0011-P**

**Re: Comments on Proposed Rule: Medicare Program: E-Prescribing and the Prescription Drug Program NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)**

Dear Dr. McClellan:

The Blue Cross and Blue Shield Association (BCBSA) appreciates the opportunity to comment on the Proposed Rule to adopt standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). BCBSA represents the 40 independent Blue Cross and Blue Shield Plans (Plans) that provide coverage to 92 million people – nearly one-in-three Americans – among them approximately one million beneficiaries in Medicare Advantage.

BCBSA strongly supports the adoption of health information technology, including electronic prescribing systems, to improve patient safety and the cost effectiveness of healthcare delivery. E-prescribing can improve the health and well-being of Medicare beneficiaries – and also help slow the rate of growth in spending – by reducing errors, increasing formulary compliance, and streamlining communications between physicians and pharmacies. Our comments are intended to help you make e-prescribing administratively practicable for providers, pharmacies and claims administrators in Medicare Part D.

**First and foremost, we urge CMS to change the January 1, 2006 compliance date to give plans the time to build the capacity for e-prescribing and ensure a smooth transition to the national standard.** CMS should allow a period of pilot testing before final adoption of standards – as provided for in the statute and as recommended by the Workgroup for Electronic Data Interchange[1] – and a sufficient implementation period after HHS has issued final rules for plans to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the

[1] *See* Letter to The Honorable Tommy Thompson from the Workgroup for Electronic Data Interchange (WEDI), dated March 8, 2004. WEDI supported and recommended the concept of using pilot implementations for future standards. Piloting identifies flaws that could be corrected before issuing final standards and determines if proposed standards actually accomplish intended goals. *Id.* at page 6.
www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/March82004LettertoDHHS.pdf

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system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

- BCBSA supports CMS choices of ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, many commercial and proprietary e-prescribing systems currently do not use these standards. It will take time to develop and deploy software that uses these standards, time to test these standards, and time to identify and correct any problems integrating 270/271 and NCPDP standards.

- Performance testing is particularly important for the 270/271 standards because relatively few providers are now originating 270 transactions for claims. For example, 2004 data on HIPAA transactions from Blue Cross and Blue Shield Plans' national accounts and traveling members show that 270 transactions comprised less than 2 percent of total HIPAA transactions.

- For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

**In addition to changing the compliance date, BCBSA urges CMS to make two other important changes:**

- Adopt a broader view of preemption that federal law preempts any state law. CMS's narrow interpretation of preemption could make e-prescribing administratively difficult for providers, pharmacies, and administrators.

- Follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. CMS's proposal unnecessarily regulates entities' internal processes, thus raising the administrative burden of supporting e-prescribing.

We appreciate the opportunity to offer these comments, which we strongly believe will make e-prescribing administratively practicable for providers, pharmacies and claims administrators, thus strengthening the overall Part D benefit. Please find attached more detailed comments, arrayed to follow the issues as presented in the NPRM.

We look forward to continuing to work with you and your staff on this and all other issues relating to the Medicare Prescription Drug Benefit.

Sincerely,

Alissa Fox

Alissa Fox
Executive Director, Policy

Attachment

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
Fax 202.626.4833

**April 5, 2005**

**Blue Cross Blue Shield Association Comments on**
**"Medicare Program: E-Prescribing and the Prescription Drug Program"**
**Proposed Rule**
**NPRM CMS-0011-P (42 C.F.R. Part 423) (70 Fed. Reg. 6256, February 4, 2005)**
**CMS-0011-P**

The Center for Medicare and Medicaid Services (CMS) requested that comments be organized by the section of the proposed rule to which they apply, using the specific "issue identifier" that precedes the section: **Background;** and **Provisions**. The order of these comments follows the issues as presented in the NPRM. Page number references are to the NPRM as published in the Federal Register on February 4, 2005.

## I. Background

### State preemption (Page 6258)

**Proposed Rule:** The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contains specific statutory language on the preemption of State laws that are contrary to the standards or restrict the ability to carry out the Part D benefit and that pertain to the electronic transmission of prescriptions and information with respect to Part D covered drugs. CMS proposes to interpret this preemption of state laws narrowly, finding that it applies only to state laws that are either contrary to the Federal standards or that restrict the ability to carry out the e-prescribing drug program requirements and pertain to electronic prescriptions and information regarding Part D drugs for Part D enrolled individuals.

**Issues:** Variations in state rules and regulations are ubiquitous. As explained in a separate letter "Comments on E-Prescribing of Drugs and Preemption of State Laws," BCBSA believes that forcing providers, pharmacies, and claims administrators to comply simultaneously with multiple state rules and the federal rule may deter use of e-prescribing, and unnecessarily raise costs and administrative burden.

**BCBSA Recommendation:** BCBSA believes that CMS should adopt a more expansive view of federal preemption confirming that federal law preempts any state law that would frustrate Congress' policy objective of fostering a uniform federal regulatory framework for e-prescribing under Part D.

### Criteria for determining foundation standards (Page 6261)

**Proposed Rule:** The MMA permits HHS to adopt standards as final without pilot testing where the Secretary can determine there is "adequate industry experience" with the standard. The MMA did not define "adequate industry experience." CMS has proposed the following criteria to assess adequate industry experience:

- American National Standards Institute (ANSI) accredited;
- Generally has been implemented in multiple e-prescribing programs with more than one external partner by entities to which the final standard will apply; and
- Recognized by key industry stakeholders as the industry standard.

**Issues**: We believe that these criteria are necessary – especially ANSI accreditation – but not sufficient to assess adequate industry experience. The HIPAA transaction experience demonstrates that systems and processes vary greatly, especially around key vendor products. Therefore, implementation in "multiple" e-prescribing programs is no guarantee that a standard can go without testing in all settings; for example, systems that work well for a chain pharmacy model may not work well for independent pharmacies or for mail order pharmacies.

**BCBSA Recommendation:** CMS should seek additional recommendations from stakeholders on how to assess adequate industry experience. CMS's view that there is adequate industry experience for the proposed foundation standards – a view that we question – is indicative of the need for added criteria.

**Identifiers (Page 6262)**

**Proposed Rule:** CMS is considering requiring the use of the national provider identifier (NPI) as the provider identifier for an e-prescription under Medicare Part D. The NPI timetable calls for HHS to begin accepting applications from providers for identifiers after May 23, 2005. Use of the NPI is mandatory starting May 23, 2007 (2008 for small health plans).

**Issue:** At this time, it appears that the NPI will not be universally available for use by January 2006. For HIPAA NPI implementation purposes, industry has proposed a "workaround" that would allow transactions to carry both the old identifier and the new NPI. However, provider and vendor systems that send billing information to the Plans may not be able to carry both the legacy identifier and the NPI by January 2006.

Plans that did not expect to have to be ready to process the NPI until 2007 may begin to receive transactions with the NPI as the only identifier and other transactions with a non-NPI identifier. Depending on the source of the transaction, plan systems would have to process the transaction using the NPI or a legacy identifier – running and maintaining duplicate systems for the interim period. Plans must be given sufficient time to migrate providers from their legacy identifiers to the providers' new NPI. Additionally, the NPI does not support the necessary transmission routing functions of electronic prescribing identifiers. Current identifiers allow for individual prescriber identification and multiple service locations. A single identifier solution for this shortcoming must be developed, assessed and tested.

**BCBSA Recommendation:** BCBSA urges that CMS move back the January 1, 2006 compliance date to permit additional time for pilot testing and implementation. This would have the added benefit of avoiding the issues created by an early implementation of the NPI for e-prescribing.

We note that the Workgroup for Electronic Date Interchange (WEDI) recommended in a September 30, 2004 letter to Secretary Tommy Thompson that no successful implementation of the NPI could occur in less than 18 months from the time the NPI is available for use, and that

no full-scale implementation should be undertaken without pilot testing the NPI.[1] We would support pilot testing use of the NPI in the e-prescribing context.

**Formulary and medication history standards (Page 6263)**

**Proposed Rule:** The NCVHS determined that formulary and medication history information are currently communicated between payers and prescribers using proprietary messages, frequently the Information File Transfer Protocols established by RxHub. On the basis of this determination and other criteria revealed in the proposed rule, CMS is proposing to adopt other standards currently under development by NCPDP as foundation standards.

**Issue:** Many Plans that intend to offer Part D benefits use commercial or proprietary formulary and medication history messaging protocols dissimilar to those that will be balloted by NCPDP. Thus, adequate industry experience is lacking.

**BCBSA Recommendation:** CMS should adopt the formulary and medication history standards currently being balloted by NCPDP as initial standards to pilot test and not as foundation standards for required use beginning January 1, 2006.

**Proposed foundation standards (Page 6264)**

**Proposed Rule:** CMS proposes to apply the "adequate industry experience" exception to specific standards regarding prescription transmissions between prescribers and dispensers and eligibility inquiries between dispensers and payors and prescribers and payors (NCPDP SCRIPT Standard, Version 5, Release 0; NCPDP Telecommunication Standard Guide, Version 5.1; and American Standards Committee (ASC) X 12N 270/271).

**Issue:** BCBSA supports using ASC X12N 270/271 and the NCPDP Telecommunication Standard. However, industry does not have adequate experience because many current commercial and proprietary e-prescribing systems do not use the 270/271 standards. These e-prescribing systems generally provide eligibility information to the pharmacy using the NCPDP telecommunication standard. It will take time to make enrollee eligibility available to physicians using the 270/271 transaction: time for software development; time for deployment; and time to identify and correct any integration problems.

For a Medicare beneficiary seeking to fill a prescription at a retail pharmacy, the lack of time to test for and correct problems could be problematic. When problems do inevitably crop up because of lack of adequate testing, beneficiaries may experience delays in service.

Lack of adequate industry experience may be a particular issue for mail order pharmacies. Communicating eligibility and benefit status to and from a dispensing pharmacy via the NCPDP telecommunications standard is currently a HIPAA required transaction standard for communications with retail pharmacies. But in mail order pharmacies, prescriptions generally arrive via fax and are entered into the mail-order pharmacy's automated fill-order system. Eligibility is determined by checking against enrollee information provided by a plan directly to the mail-order pharmacy and not through an on-line inquiry system built to the NCPDP

[1] *See* "WEDI NPIPAG Recommendations, August 26, 2004," Issues 1 and 3. A copy of this correspondence can be found at http://www.wedi.org/cmsUploads/pdfUpload/commentLetters/pub/093004NPIFinalEDJR.pdf .

Telecommunications Standard. These processes operate on computer programs written to code not interoperable with e-prescribing software.

**BCBSA Recommendation:** While BCBSA supports the selection of specific appropriate standards for e-prescribing functions, we urge CMS to support a period of pilot testing (for at least one year) to ensure that the 270/271 standards will perform as desired when integrated into an e-prescribing systems with the NCPDP Telecommunication standards. Also, we urge CMS to provide for an implementation period (the statutory timetable would suggest 24 months) that gives plans sufficient time to make systems changes and to conduct installation testing (to verify that the physical installation of the system meets the defined requirements), operations testing (to verify that the system performs the defined functionality), and performance testing (to verify that the system will operate at maximum volume and system stress).

## II. Provisions

### Definitions (Page 6265)

**Proposed Rule:** CMS proposes the following definition:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals who are enrolled in Part D plans.

**Issue:** The definition reflects the narrow state preemption analysis proposed by CMS to govern conflicts with state laws. Under the proposed definition, an e-prescribing program is limited to Part D drugs prescribed for Part D eligibile individuals who are enrolled in Part D Plans. The adopted standards would then apply only to this narrow set of drugs and individuals.

**Recommendation:** BCBSA recommends that the definition of a Electronic Prescription Drug Program be revised as follows:

> **Electronic Prescription Drug Program** means a program that provides for e-prescribing for covered Part D drugs prescribed for Part D eligible individuals.

### Communication in closed networks (Page 6265)

**Proposed Rule:** CMS would require e-prescribing communications internal to an organization be communicated in compliance with the adopted NCPDP Script standards for e-prescribing for Part D drugs. The NCVHS had recommended that organizations that conduct e-prescribing internally should not be required to convert to the standards to be adopted by CMS for Medicare Part D for prescription communications within their enterprise. CMS notes that the NCVHS recommendation differs from the HIPAA transaction rule requirement that a "covered entity" conducting a covered transaction using electronic media within the same covered entity must conduct the transaction as a standard HIPAA transaction.

**Issue:** BCBSA is concerned with CMS' decision not to follow the NCVHS recommendation that an organization's internal communications not be covered by the rule. BCBSA's general approach to health information technology is that transaction rules should not dictate internal processing but should ensure standardizing the interfacing between differing organizations' systems for market interoperability.

**BCBSA Recommendation:** CMS should follow the recommendations of the NCVHS and recognize that the exchange of prescription information within the same enterprise is outside the scope of the MMA requirements.

**Backward compatibility (Page 6267)**

**Proposed Rule**: HHS is proposing to consider waiving notice and comment rulemaking when updates or newer versions of standards are "backward compatible" (i.e., entities using the newer version would be able to complete transactions with entities using the the previous version). In this case, CMS would likely permit the version that was previously adopted and the new version as equally compliant at the same time.

**Issue:** In general, an entity using the older version of a standard cannot process the newer version without further system changes, such as the addition of translation software – even when the newer version does not include substantive changes such as new functions. True backward compatibility occurs when the entity adopting the new version pays for the translation software. However, the CMS definition of backwards compatibility could be construed as absolving the entity adopting the new version of the obligation of paying for that translation software, thus inadvertently penalizing entities that choose to keep the previously adopted standard.

**BCBSA Recommendations:** CMS should make clear that the obligation to produce transactions that an entity with a previously adopted versions can process lies with the entity that chooses to migrate to the newer version. CMS should not find backward compatibility where no provision has been made in the standard to ensure that entities with previously adopted versions can process those transactions sent from entities using newer versions.

**Linking e-prescribing standards updates to HIPAA standards updates (Page 6267)**

**Proposed Rule:** CMS proposes to coordinate the updating process for those e-prescribing standards that are also HIPAA transaction standards.

**Issue:** Linking the e-prescribing standard update to the HIPAA standards update would provide administrative simplicity for CMS and reduce the compliance burden for the affected industries and covered entities.

**BCBSA Recommendation:** BCBSA supports having the e-prescribing standards updates tied to the HIPAA updates. This allows entities to monitor one point for future proposed changes. It also avoids getting HIPAA and e-prescribing out of synch and into conflicting requirements.

**Compliance date (Page 6267)**

**Proposed Rule:** CMS proposes making compliance with the e-prescribing standards proposed in this rule mandatory on Part D sponsors and MA/PD plans as of January 1, 2006.

**Issue:** BCBSA believes that January 2006 is not a reasonable compliance date for implementation of these proposed new foundation standards See "Proposed foundation standards" above

**BCBSA Recommendation:** See "Proposed foundation standards" above.

April 4, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: Comments on Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256 (Feb 4, 2005) [CMS-0011P]**

Dear Administrator McClellan:

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is pleased to submit comments on the first proposed rule on electronic prescription system standards ("the Proposed Rule") under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the MMA"). PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier and more productive lives. PhRMA companies are leading the way in the search for cures, and are committed to the successful implementation of the Medicare prescription drug benefit.

## Introduction

Section 1860D-4(e)(1) of the Social Security Act ("SSA") requires that any electronic prescription ("e-prescription") used to provide Part D covered drugs to a Part D eligible individual meet e-prescription standards developed by Health and Human Services. Additionally, under proposed 42 CFR § 423.159(c), all sponsors of Medicare prescription drug plans must "support and comply" with these e-prescription standards once they take effect.

The Proposed Rule is the first of several anticipated rules that will be used to establish e-prescription standards. It identifies three existing standards that will constitute "foundation" standards for e-prescribing, which will not have to be pilot tested before being adopted as final standards. In general, the MMA calls for e-

prescription standards to be pilot tested during calendar year 2006, before being adopted.[1] Testing is not required, however, "where there already is adequate industry experience with" the standard at issue.[2] Many of the our comments are in response to requests for comments on the standard development process in general, particular standards that will be developed in future rules, and the criteria used to determine whether adequate industry experience exists for a particular standard.

**Overview of Comments**

Because the e-prescription standards will be developed in a step-wise fashion, it will be critical, from the beginning of the process, to have explicit design principles to guide development of the individual standards. Absent such principles, the standards as a whole may be incomplete, inconsistent or even counter-productive. The first comment presented below ("Design Principles for an E-prescription System") recommends a set of principles to be used for this purpose.

It also will be important to have a clear idea of the number of standards required, and the scope of each standard. If these parameters are not clear, the resulting set of standards may be incomplete. Comments 2 and 3 ("Critical Aspects of An E-Prescribing Transaction" and "Standards Required for an E-prescription System") describe the range of standards required.

To evaluate the e-prescription system, it will be necessary to assess the value of a given standard or combination of standards. The cost of the drugs prescribed under the system is only one element of its value. For example, the extent to which the e-prescription system is accepted and used by prescribers, the time and other resources prescribers and dispensers save by performing essential functions electronically, and the impact on the overall cost of treatment (including a decrease in the cost of non-drug therapies as drug therapies are used more effectively) all will play a role in determining the system's value. A number of these factors are set out in Comment 4 ("Factors To Consider in Assessing Value"). The factors also may be considered to evaluate proposals for individual standards.

The next seven comments are narrower in focus. Comment 5 ("Definition of 'Adequate Industry Experience'") addresses the criteria that should be used to determine whether pilot testing should be suspended for a given standard (i.e., whether the standard should be designated a "foundation" standard), while Comment 6 discusses the proposed NCPDP Formulary and Benefit Standard. Comment 7 addresses whether the e-prescription system should support prior authorization of prescriptions. Comments 8 and 9 address issues that may be

[1] SSA §1860D-4(e)(4)(c)(i).

[2] SSA §1860D-4(e)(4)(c)(II).

raised by forthcoming standards for drug information and messages, and Comment 10 discusses information about lower cost therapeutically appropriate alternatives. Comment 11 discusses the direct cost of an e-prescription system to pharmaceutical manufacturers (for purposes of determining the cost impact of the proposed rule).

The final three comments concern the process used to develop and implement an e-prescription system. Comment 12 recommends principles for maintaining adequate stakeholder involvement in this process. Comment 13 discusses the use of formal rulemaking, while Comment 14 discusses the limited circumstances under which standards may be updated without formal rulemaking.

**Comments**

**COMMENT 1: DESIGN PRINCIPLES FOR AN E-PRESCRIPTION SYSTEM**
**(Responds to BACKGROUND, Sections F and G)**

We believe that an e-prescription system should be designed to embody the following principles.

1. **An e-prescription system should be designed to improve patient care and strengthen the physician-patient relationship.**

   - ***Put the patient first.*** The system should be designed to ensure patient safety (for example, by helping to avoid adverse drug-to-drug interactions), improve the quality of care, and promote the efficient delivery of prescription drugs.

   - ***Protect patient privacy.*** Privacy and confidentiality are important concerns throughout the health care delivery system. An e-prescription standard should ensure adequate security and privacy measures.

   - ***Promote physician-patient communication.*** The system should facilitate a dialogue between the provider and the patient at the point of care. Patients have individual clinical needs, life circumstances, and personal values that influence their medical care. A dialogue at the point of care will help the physician to choose an appropriate drug therapy and increase patient compliance with that therapy.

   - ***Preserve the physician's role.*** The system should support the clinical judgment of physicians (and other drug prescribers). Preserving the physician's autonomy to select the right therapy for a patient is critical to preserving the physician-patient relationship and achieving quality medical care.

2. **An e-prescription system should provide information when it is needed.**

   - ***Provide the information needed by physicians.*** An e-prescription system should provide physicians with the information needed to discuss drug therapy with the patient at the point of care. The system also should allow the physician to perform functions that will determine what drugs are available, such as prior authorization and eligibility verification, at the point of care.

   - ***Provide the information needed for beneficiary protection.*** An exceptions and appeals process is an important protection that allows beneficiaries to access needed medications. An e-prescription system should enable the beneficiary to receive immediate notice of the right to request an exception or appeal, and the information required to do so.

   - ***Work with other electronic health information systems.*** An e-prescription system should be compatible with the electronic health record (EHR) systems that currently are being refined and standardized. This would allow information to be exchanged between the two systems. For example, the e-prescription system could import information about prior drug therapies from an individual's EHR to add to the individual's medication history.

3. **An e-prescription system should be designed to reduce the overall cost of care.**

   - ***Consider the full range of cost savings.*** The e-prescription standards should promote a system design that serves to maximize all the potential savings available through the improvements in patient safety, quality of care and cost-effectiveness. For example, using drug therapies more effectively will reduce inpatient admissions, which results in cost savings throughout the health care delivery system. Eliminating fraud and abuse likewise will reduce overall health care costs.

   - ***Provide value to all parties using the system.*** The e-prescription standards should not impose an undue administrative burden on health care professionals or dispensing pharmacies and pharmacists, or otherwise discourage them from using the e-prescription system.

   - ***Cover the entire prescribing process.*** The system should enable system participants to perform all of the significant steps in the prescribing process (such as prior authorization) more efficiently. Simplicity is likely to be a significant factor in determining whether prescribers embrace e-prescribing; they are less likely to do so if they still must resort at times to an alternative system that is not available at the

point of care. The value of the system also would be enhanced if it supported "Fill Status Notification" transactions that allow prescribers to determine whether prescriptions that have been written actually have been filled and received by patients.

**COMMENT 2: CRITICAL ASPECTS OF AN E-PRESCRIBING TRANSACTION**
**(Responds to BACKGROUND, Sections F and G)**

E-prescribing standards may regulate three different aspects of an e-prescription transaction: (1) content, (2) integrity and (3) display.

1. ***Content*** refers to the types of information contained in the transaction, its format and (when appropriate) the use of standardized codes for certain types of information. Content issues include the following:

   - What types of information are needed to support all of the functions accomplished through the transaction? Is all of the information required to support the function being conveyed?

   - Is the information suited to its intended audience (prescriber or dispenser)?

   - Is the information ambiguous or misleading?

2. ***Integrity*** refers to the accuracy and reliability of the information being conveyed. Integrity issues include the following.

   - Is the information complete? The system should provide all of the information of a given type that is required for the prescriber or dispenser to perform the function at issue. It is especially important that information directly involved in treatment (such as medication history and medical history) be complete even though it may be drawn from a number of different sources.

   - Is the information up-to-date? This requirement also will vary with the type of information and the purpose for which it is used. For many types of information directly used in treatment, this is an especially important concern.

- What is the source of the information? If the information incorporates judgments, is the source knowledgeable enough and objective enough to make accurate judgments?

- Should the information be certified by a third party, or produced according to a process set forth by CMS, in order to ensure its accuracy? Relying on existing third-parties with the expertise and objectivity to perform this function could simplify the standards and the standard development process.

3. ***Display*** refers to the manner in which the transaction is presented to the prescriber or dispenser who will be using it; it includes both the appearance and arrangement of the information in the display (including the use of pop-up menus and other devices that emphasize certain information) and the steps that the prescriber or dispenser must follow to navigate through the information. Display issues include the following.

   - Could the manner in which the information is displayed inappropriately influence the prescriber or dispenser who receives it? For example, does the system initially display only certain drugs in the formulary to reduce the likelihood that the prescriber will evaluate (and possibly choose) other clinical options?

   - Does the manner in which the information is displayed place a burden on the prescribers or dispensers who use the system? For example, is it more technologically cumbersome or inconvenient to prescribe certain drugs because the prescriber must navigate through more screens or respond to additional prompts?

   - Does the display impede decision-making (prescriber, patient)? For example, do pop-up messages repeatedly appear and disrupt the prescriber's normal decision-making process?

   - Is one display suitable for all users or should users control the display to some extent?

For several reasons, the standards proposed in the Proposed Rule address content issues rather than integrity or display issues. This focus is appropriate: the transactions governed by these standards convey objective information rather than judgments or assessments, and the information in each transaction is derived from a single source. As a result, concerns with the integrity of the information are minimized. The information conveyed also is relatively simple and straightforward, which likewise minimizes concerns about its display.

Other standards required for a fully functional e-prescription system, however, will raise integrity and display issues. This is especially true of standards that provide information integral to the prescribers' deliberations (such as medication and medical history, as well as messaging), which typically will convey judgments of some kind. Consequently, even at this early stage of the process, it is appropriate to consider how those concerns will be addressed and integrity and display will be regulated.

As indicated in the appendix to these comments, parties testifying before the National Committee on Vital and Health Statistics (NCVHS) already have been looking ahead to these issues. Among these looming issues are the following.

- Will the NCVHS evaluate and make recommendations concerning integrity and display issues?

- Will candidate standards from existing standard development organizations address integrity and display issues? If these candidate standards do not (possibly because the organizations historically have focused exclusively on content concerns), how will CMS develop integrity and display standards? Will the agency develop the necessary standards itself or look to other organizations that have been more concerned with such issues?

- Are traditional standards the best approach to regulating integrity and display concerns? Alternatively, would third-party review and certification, or standards that limit the process by which the information is developed or compiled, be better than a prescriptive standard?

## COMMENT 3: STANDARDS REQUIRED FOR AN E-PRESCRIPTION SYSTEM

**(Responds to BACKGROUND, Sections F and G)**

The following table indicates the number of distinct standards required to establish an e-prescription system with the range of functions contemplated by the MMA. The Proposed Rule identifies foundation standards for the first two types of information, prescription information and eligibility information.

Our comments pay special attention to the forthcoming standards required to regulate Drug Information and Messaging. While not discussed in detail in the Proposed Rule, these standards will be relatively complex and raise special concerns about the integrity of the information that is conveyed and the way this information is displayed. Consequently, even at this early point in the process, it is appropriate to think about the general approach that should be followed to develop these standards.

**Table: E-Prescription Standards Required**

| *Type of Information Transmitted* | *Existing Standard* | *Content Concerns* | *Integrity Concerns* | *Display Concerns* |
|---|---|---|---|---|
| ***Prescription*** – SSA § 1860D-4(e)(2)(A) | NCPDP SCRIPT | No | No | No |
| ***Eligibility*** – SSA § 1860D-4(e)(2)(A) | X12N 270/271 | No | No | No |
| ***Telecommunications*** – | NCPDP Telecomm'ns | No | No | No |
| ***Formulary & Benefit Coverage*** – SSA § 1860D-4(e)(2)(A) | NCPDP F&B (proposed) | Yes | Yes | Yes |
| ***Prior Authorization*** – SSA § 1860D-4(e)(2)(A) | No | Yes | No | Yes |
| ***Medication History*** – 70 Fed. Reg. 6263 | NCPDP Med. History(proposed) | Yes | Yes | No |
| ***Medical History*** – SSA § 1860D-4(e)(2)(B) | No | Yes | Yes | No |
| ***Drug Information*** – SSA §1860D-4(e)(2)(A)(I), (3)(C)(III) | No | Yes | Yes | Yes |
| ***Messaging*** – SSA § 1860D-4(e)(3)(D) | No | Yes | Yes | Yes |

## COMMENT 4: FACTORS TO CONSIDER IN ASSESSING VALUE
**(Responds to BACKGROUND, Sections F and G)**

Both during pilot testing and once the e-prescription standards are finalized, CMS should collect and evaluate data used to estimate the value added by the e-prescription system. Value will be added not only by reducing the cost of prescriptions but by improving the quality of care and the overall efficiency of the prescription process. It is important to consider the following types of data, which would be overlooked if prescription drug "line item" costs are regarded as the sole measure of value:

- The level of use by (and direct feedback from) prescribers. Prescribers are not required to use the e-prescribing system and presumably do so only if it provides advantages over non-electronic methods.

- Prescribers' and dispensers' estimates of cost savings.

- Positive feedback from patients (for example, reports of improved dialogue with providers about drug therapies).

- Improved persistence and adherence to drug therapies.
- The reduction in medication errors (include undesirable drug-to-drug interactions).
- The reduction in communications about prescriptions outside of the e-prescription system (such as telephone inquiries from dispensers to prescribers).
- The extent to which essential steps in the prescribing process may be performed through the system, without recourse to alternative methods (such as telephone inquiries).
- Ways in which the system may be used to monitor and combat fraud and abuse.
- The extent to which the system allows access to relevant data for legitimate research activities.
- The change in total treatment costs (including reduced non-drug treatment costs due to the more effective use of drug therapies).

**COMMENT 5: DEFINITION OF "ADEQUATE INDUSTRY EXPERIENCE"**
**(Responds to BACKGROUND, Section F)**

E-prescription standards generally are subject to pilot testing. This requirement is waived, however, if there is "adequate industry experience" with the standard at issue. The Proposed Rule proposes the following criteria for assessing whether adequate industry experience exists.

(1) The standard is American National Standards Institute (ANSI) accredited;

(2) The standard generally has been implemented by the entities that will be subject to it once it is adopted for e-prescribing purposes;[3]

(3) The standard is recognized by key industry stakeholders as an industry standard.

While CMS has the authority to designate foundation standards, it should not do so mechanically. Identifying foundation standards can expedite implementation if those standards in effect have already been tested. Weakening these criteria would only delay implementation by preventing needed testing from taking place.

[3] Because this requirement is intended to identify standards which have been implemented successfully in a context comparable to e-prescribing, these entities as a whole must implement the standard in multiple programs, each with multiple participants. 70 Fed. Reg. 6261.

Consequently, we believe that these criteria should be not only maintained but strengthened. Specifically:

(1) The ANSI accreditation requirement should be maintained even if there are no ANSI accredited candidates for a particular standard. As the Proposed Rule notes, the ANSI accreditation process is open to all entities that may be regarded as stakeholders in the e-prescription system. In addition, the ANSI standard development process is consensus based, which encourages broad participation in standard development. Abandoning the requirement increases the risk that some stakeholders may not have a meaningful opportunity to participate in the development process.

(2) The standard should not only have been implemented but have been used for a volume of transactions that suggests that it will be capable of functioning in a fully deployed e-prescription system. In other words, the transaction volume (while possibly less than anticipated for e-prescribing) should suggest a mature, commercial program and not an experimental program of limited scope. In addition, CMS should consider the length of time that the standard has been implemented.

(3) CMS should consider whether all of the possible stakeholders in the e-prescription system (and not just a small group of "key" stakeholders) have embraced the standard. To begin with, it is unclear how CMS will determine what "industries" to consider. Entities other than prescribers and dispensers will play a meaningful role in supporting the e-prescription system. Medication and medical information, for example, may have to be collected from sources that are not serving as prescribers or dispensers, but will have to accommodate the standards for that information to perform their role effectively. Perhaps most importantly, the e-prescription system will have to be compatible with electronic health record systems that have yet to be fully deployed. Incorporating standards that are accepted across health care industries increases the chance that an e-prescription system will be compatible with other electronic health information standards.

There is an advantage to designating foundation standards when testing is simplified as a result. This usually occurs when the standard at issue is self-contained. The X12N 270/271 standard, for example, fully describes the eligibility inquiry and response transactions without referring to other standards. As a result, if they are designated as foundation standards, there is no need to test the eligibility transactions at all. If a given standard is only one of several that govern a particular transaction, however, designating it as a foundation standard will have a very limited impact on testing. The transactions will still have to be tested to determine whether the other standards are appropriate and interact effectively. The development process may even be complicated because the foundation standard is finalized early and cannot easily be modified to fit better with the others.

## COMMENT 6: THE PROPOSED NCPDP FORMULARY AND BENEFIT STANDARD

**(Responds to BACKGROUND, Section F)**

According to the MMA, e-prescriptions should accommodate information on "the availability of lower cost therapeutically appropriate alternatives (if any) for the drug prescribed." As discussed in detail in Comment 10, "Information on Lower Cost Therapeutically Appropriate Alternatives," the e-prescribing system will provide several types of information (such as the detailed information provided about additional drugs) that will be helpful to a physician who is evaluating different drug options for a patient.

Attempts to include additional statements about alternative drugs would not be helpful, and may even have negative consequences. In light of these concerns, we recommend that the version of the Formulary and Benefit Standard adopted by CMS not include the "Formulary Alternatives List" contained in the current NCPDP version. The "Formulary Alternatives List" could be used to suggest – erroneously – that certain drugs are interchangeable. Use of this list is not regulated by the standard itself.

## COMMENT 7: PRIOR AUTHORIZATION

**(Responds to BACKGROUND, Section G)**

If a prior authorization requirement is imposed upon a particular drug, the e-prescribing system should allow a prescriber to request prior authorization and learn, at the point of care, whether that request is successful. The MMA requires that the system avoids placing any undue burden on the prescriber, and for good reason: simplifying the prescribing process will promote clinically appropriate decisions. But the value of an e-prescribing system will be compromised if prescribers are forced to use an alternative method for prior authorization that is not available at the point of care.

To ensure e-prescribing's success, it is critical that the final system fully supports electronic prior authorization for those drugs subject to the requirement. Because this would be a significant advance over existing systems, electronic prior authorization should be included and tested in the 2006 pilots. From the time it first becomes fully operational, for those drugs subject to prior authorization requirements, the e-prescribing system should allow prescribers to perform the entire prior authorization process through the system.

Since full support for prior authorization is not possible at this time, the capabilities of the proposed foundation standards adopted prior to pilot testing should be utilized to provide some degree of support for prior authorization. Specifically, the proposed NCPDP Formulary and Benefit

Standard contains 100- and 200-character free text fields ("Message - Short" and "Message - Long") and a resource link field, which are intended to support several different functions. These fields can be used to provide drug-level information on prior authorization requirements. The resource link field could also be used to provide the prescriber with a hyperlink to a web site used to complete and submit the prior authorization request. CMS should require all plans that use the Formulary and Benefit Standard to use these fields to provide coverage-specific and drug-specific information for all drugs that require prior authorization. We emphasize, however, that this approach is only an interim solution to be used while full support for electronic prior authorization is being developed through pilot testing.

**COMMENT 8: STANDARDS FOR DRUG INFORMATION**
**(Responds to BACKGROUND, Section G)**

All of the drug information required by entities using the e-prescription system, including (but not limited to) information on drug-to-drug interactions, can be derived from drug labels that meet the requirements proposed by the Food and Drug Administration (FDA). On December 22, 2000, FDA proposed a new rule to change the content and format of the drug label, which has been under development since that time.[4] The final version of this rule should result in a more user-friendly presentation of important information that physicians need.

These new requirements dovetail with initiatives to develop an electronic format for drug labels. For the past five years, PhRMA has led an initiative to deliver electronic drug labels to dispensing sites. At the current time, FDA regulations require paper drug labels to be affixed to all package units delivered to the pharmacy.[5] These labels are unwieldy and there is no guarantee that they contain the most current information on the drug. Through the HL-7 ANSI-accredited standard development organization, the Structured Product Label (SPL), which will meet the requirements of the new FDA rule, is under development; Version 1.0 was approved late last year and Version 2.0 will be coming up for balloting this spring. A final SPL standard will provide the impetus for industry to submit labels to FDA in electronic format.

FDA presently is constructing an information technology system that will expedite the transmission and review of electronic drug labels. Part of this will be a new initiative that will post the most current drug labels on the National Library of Medicine website. In addition to promoting the general goal of improving the safety and quality of medication management, this new initiative will provide a repository for label information that can be utilized by an e-prescription system.

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[4] 65 Fed. Reg. 81082 ("Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels").

[5] 21 C.F.R Sec. 201.100.

Given that the SPLs will be readily available (to other electronic health care systems as well as the e-prescription system) and meet the most up-to-date label requirements, we recommend that drug information available through the e-prescription system consist of the drug's SPL. To avoid confusion, information should not be added or reformatted.[6] This requirement ensures that the information will be accurate, appropriate and displayed in a manner that prescribers will understand. It also ensures compatibility with other electronic health information systems that utilize SPL information.

**COMMENT 9: STANDARDS FOR MESSAGING**
**(Responds to BACKGROUND, Section G)**

Messaging raises a wide range of issues. Messaging could be a valuable tool for ensuring that prescribers have appropriate information about drug choices, such as warnings about adverse drug interactions and instructions helpful in selecting drugs for an individual patient (for example, whether drugs should be taken with food). Given the MMA's restriction on advertising, however, messaging raises content issues. Because these messages may contain judgments or compilations of information, integrity issues also arise. Finally, because the way that information is presented strongly affects its impact (imagine, for example, a pop-up message that requires several steps to close) there also will be issues about how the information is displayed.

It is critical that the standards embody the MMA's prohibition on commercial messaging. Messages may contain only information that "relates to the appropriate prescribing of drugs," including information intended to reduce medication errors and adverse drug interactions, and "improve medication use" (such as information provided under quality assurance measures or systems established pursuant to MMA Section 1860D-4(c)(1)(B)). The e-prescription system may not be used "as a marketing platform or other mechanism that could unduly influence physicians' clinical decisions."[7] Instead, providers should have "ready access to neutral and unbiased information on the full range of covered outpatient drugs available."[8]

Messaging requirements will vary depending on the timing and direction of the message. Given the MMA's restriction on advertising, it is especially important to scrutinize messages directed to the prescriber. Messages that appear before the

[6] Information presented in addition to the SPL should be regarded as one or more messages and must satisfy the standards that apply to messages. This distinction between drug information, defined simply by reference to a drug's SPL, and messaging will simplify the standards without limiting the total amount of information that can be provided.

[7] Conference Report at 455 (for real-time transmission); Letter from Senator Grassley to NCVHS, *Implementation of the Medicare Modernization Act (MMA) Electronic Prescribing Program* of 7/26/04.

[8] Id.

prescriber begins the decision making process (for example, those that appear as soon as the system is activated) are less likely to convey specific information used in prescribing. These messages should be regulated carefully to prevent advertising. Messages contained in a "Change Request" transaction sent to the prescriber after he or she has transmitted a prescription also are suspect. Unless the transaction identifies an error (or potential error, such as an undesirable drug interaction), it likely is intended only to pressure the prescriber to change his or her earlier drug decision.

Messaging standards also may distinguish several different types of messages based on the information they contain. For example, messages that convey warnings about drug interactions or possible allergic reactions could always be displayed in a way that would be certain to attract attention, such as pop-up windows. Prescribers would be free, however, to control how messages that contain less critical information are displayed or even to suppress them. (Prescribers are less likely to use the system if they expect to be confronted by a stream of inconvenient or inappropriate messages.)

These are only preliminary observations; the process of developing appropriate messaging standards is just beginning. To avoid confusion, however, messages should not be allowed in e-prescription transactions, even during pilot testing, until adequate standards for the content, integrity and display of these messages have been developed. These will be wholly new standards and, once developed, they should be pilot tested carefully.

As CMS speakers at the March 1, 2005 Open Door Forum on E-Prescribing indicated, some of the steps a plan could take influence or develop a messaging system—for example, contracts with software vendors affect messaging—should be regulated as marketing practices. That type of regulation and standards governing the content, integrity and display of the messages are complimentary and equally important. Ongoing regulation of marketing activities would prevent a plan from establishing an infrastructure in which advertising could exist. The messaging standards themselves, however, will still be needed to provide clear and detailed guidance on what information messages can contain and how they can appear.

**COMMENT 10: STANDARDS FOR INFORMATION ON LOWER COST THERAPEUTICALLY APPROPRIATE ALTERNATIVES**
**(Responds to BACKGROUND, Section G)**

According to the MMA, e-prescriptions should accommodate information on "the availability of lower cost therapeutically appropriate alternatives (if any) for the drug prescribed." The e-prescription system will provide several types of information to help a physician identify drug treatment options. The first is information about the individual drugs. As recommended in these comments, the system should provide access to Structured Product Labels (SPLs) that contain

all of the information that soon will be required by the FDA.[9] The SPL will provide information about the uses and efficacy of the drug, various drug properties (such as absorption, bioavailability and route of elimination) and drug-to-drug interactions. Using SPLs as the source of this information ensures that physicians will receive important drug information in a familiar and user-friendly format.

The second type of information is the formulary design itself. The formulary classifies drugs based on properties at a population level, while cost-sharing tiers provide information about costs. The judgments reflected in the formulary have been made by the plan's Pharmacy and Therapeutics Committee (P&T Committee). Specific requirements concerning the composition and conduct of P&T Committees are designed to ensure that these judgments are deliberate and based upon relevant clinical evidence. By making formulary information available to physicians, the e-prescription system will be providing population-level information about "lower cost therapeutically appropriate alternatives (if any)."

A symbol incorporated into the information about a brand-name drug that indicates that an AB-rated generic form of the drug exists also would be helpful to physicians. From a physician's perspective, these symbols would be easy to understand and unambiguous; for system designers, they would be easy to develop and implement. They could be used both in the system used for pilot testing and in the final version of the e-prescription system.

All of the information discussed so far will be helpful to a physician who is evaluating different drug options for a patient. Further attempts to identify specific therapeutic alternatives, however, would not be, and risk overriding the carefully crafted P & T Committee structure and role. There is no generally accepted definition of a "therapeutically appropriate alternative," and it is unclear just what considerations would determine which drugs are assigned this label.[10]

Even drugs with the same mechanism of action will differ in a number of ways that may be clinically significant for a specific patient.[11] These differences include but are not limited to dosing, drug-to-drug interactions, absorption (the route by which the drug moves toward the intended receptors), bioavailability (the amount of the drug that is available at the intended receptors), metabolism, route

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[9] For a more detailed discussion of this recommendation, see Comment 8, "Standards for Drug Information."

[10] Pharmaceutical manufacturers may not state that a drug is comparable to or better than another drugs unless they have specific information on this point that is accepted by the FDA, and such statements themselves are subject to FDA regulation. To ensure its validity, any claim that two drugs are therapeutically appropriate alternatives should be subject to standards of review that are at least this high.

[11] Due to these differences, a drug does not receive FDA approval because it is uses the same mechanism of action as another drug that has been approved. Extensive clinical trials are necessary to demonstrate the safety and effectiveness of the new drug.

of elimination (the route by which the drug is eliminated from the body, for example liver or kidney), indications, contraindications and side effects. In many cases, these differences will be dispositive in choosing a drug for a particular patient. For instance, a patient taking several drugs metabolized through the cytochrome P450 isoenzyme pathway may have difficulty with an additional drug metabolized through the same pathway, leading a physician to select a drug from the class that is metabolized through a different pathway. Additionally, drugs that appear comparable when evaluated at the population level display significant differences in effect at the subpopulation or individual level. [12]

Moreover, the issue of lower cost is itself highly uncertain, with results potentially varying widely based on whether the measure of cost is unit cost of the medicine, total cost of a course of medication therapy, total cost of a course of therapy to which a patient adheres, or total health care costs over varying periods of time.

As noted above, the MMA and the final Part D rule contain detailed requirements concerning the role, composition and procedures of P&T Committees and committees operating under these rules essentially present their view of lower cost therapeutic alternatives at the population level in structuring formularies. Inconsistent claims about drug alternatives developed outside of the P&T Committee's formulary development process risk undermining the committee's role and determinations.

In light of these issues, we recommend that the version of the Formulary and Benefit Standard adopted by CMS not include the "Formulary Alternatives List" contained in the current NCPDP version. The "Formulary Alternatives List" could be used to suggest – erroneously – that certain drugs are interchangeable. Use of this list is not regulated by the standard itself.

Showing two drugs as members of the same drug class also may imply – again, incorrectly – that they are equivalent. This implication would be confusing; as mentioned above, even drugs that are comparable in some respects may be significantly different in a number of others. To prevent what in effect are unregulated claims about therapeutic equivalence, we recommend that the CMS limit the taxonomies that may be used to classify drugs for e-prescription purposes. For example, CMS could establish a list of acceptable taxonomies (possibly those currently being used in e-prescribing software).[13] In addition, any

[12] See, e.g., Haiden Huskamp, "Managing Psychotropic Drug Costs: Will Formularies Work?" *Health Affairs* 22:5, 84-96, September/October 2003; William Evans and Howard McLeod, "Pharmacogenomics – Drug Disposition, Drug Targets, and Side Effects," *New England Journal of Medicine*, 348, 538-49, February 6, 2003.; and David Nash *et al.*, "Why the Elderly Need Individualized Pharmaceutical Care," Office of Health Policy and Clinical Outcomes, Thomas Jefferson University, April 2000.

[13] Present-day e-prescription software incorporates taxonomies that are used to organize information about specific drugs by drug class. These taxonomies are chosen by the software vendor and usually drawn from a handful of widely used taxonomies (such as those developed by FDB, MediSpan or Multum). Rather than being part of the data stream transmitted to the

e-prescription system that classifies drugs should provide ready access to drug information, which will indicate the similarities (and dissimilarities) that exist between the drugs in each class.

## COMMENT 11: DIRECT COST OF AN E-PRESCRIPTION SYSTEM TO PHARMACEUTICAL MANUFACTURERS

**(Responds to IMPACT ANALYSIS, Section F)**

In its current form, the Proposed Rule appears to have little direct cost impact on pharmaceutical manufacturers. Manufacturers will not be directly involved in the transactions governed by the standards identified by this rule. Consequently, there should be no need to implement or otherwise adjust to those standards.

Other e-prescribing standards, however, may have a significant impact. For example, manufacturers will soon be making a substantial investment both to comply with the anticipated Food and Drug Administration (FDA) rule on the content and format of drug labels and to implement the electronic Structured Product Label (SPL) that currently is under development.[14] If e-prescribing standards required manufacturers, either directly or indirectly, to compile information of a type or in a format other than that required for the SPL, manufacturers will be faced with the additional cost of meeting a second, possibly inconsistent standard. To assess the cost of e-prescribing accurately, CMS should continue to inquire about the possible cost to manufacturers as each e-prescribing standard is announced.

## COMMENT 12: PRINCIPLES FOR ENSURING ADEQUATE STAKEHOLDER INVOLVEMENT

**(Responds to BACKGROUND, Section F)**

The MMA's e-prescription system promises higher quality medical care with fewer prescription errors and lower medical costs. It also will serve as a model for similar systems including e-prescription systems used outside of Medicare. For both of these reasons, it is important that the MMA's system be designed well.

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prescriber, this information typically is contained in support files stored on the device used for e-prescribing, which are updated periodically.

[14]The new FDA requirements have been under development since December 22, 2000, when FDA first published its proposed rule on the topic (65 Fed. Reg. 81082, "Requirements on Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Prescription Drug Product Labels"). The SPL is being developed through HL-7, an ANSI-accredited standards organization. Version 1.0 was approved late last year; Version 2.0 will be coming up for balloting this spring. The SPL standard will provide the impetus for industry to submit labels to FDA in electronic format.

The e-prescription system contemplated by the MMA is more sophisticated than any current e-prescription system, and adequate standards do not exist for many of its components. The key to designing a successful system is input from stakeholders of various types, with different expertise and insights. The following principles would help CMS to create an infrastructure that enables stakeholders to play a meaningful role in the development process.

- ***Create and publicize a blueprint for the e-prescription system.*** This system blueprint would identify the different standards that will be required and the scope of each standard. Although it would be difficult to predict the timing of each standard precisely, the blueprint should indicate the sequence in which the standards would be developed and any events that must take place before a particular standard could be developed (for example, the release of NCVHS recommendations concerning the standard). Step-wise development is far easier if all stakeholders understand what steps will be involved. This system blueprint will enable stakeholders to predict when input of various types is appropriate, and help CMS to ensure that sufficient time and attention are allocated for each system component.

- ***Provide clear and consistent guidance.*** E-prescribing rules and standards issued by HHS should be unambiguous, easy to understand, and consistent. The guidance should address all obvious areas of concern, such as commercial messaging, patient privacy, and access to necessary medical information.

- ***Engage all stakeholders.*** Physicians, pharmacists, patients, software vendors and all other entities affected by the rules and standards should be given an opportunity to comment upon them before they are finalized. Providing all of these stakeholders with an opportunity to be involved in standard development will maximize the chance of a positive response to the final standards. Once the rules and standards are finalized, the stakeholders should be given adequate time to implement them.

- ***Promote pilot-testing.*** Although standards may be commonly used and therefore considered well established, they should be pilot-tested prior to adoption. This testing will smooth the implementation process; using familiar standards together raises issues that did not exist when the standards were used separately, and even commonly used standards may be new to a significant number of stakeholders. CMS should elicit stakeholder input on the steps involved in testing as well as the standards to be tested. Testing should involve the Medicare population and the prescribers and dispensers who serve them.

- ***Be proactive about coordinating the activities of different groups within HHS.*** Various groups within HHS should work together to identify and resolve issues (e.g. relating to patient privacy) raised during the development of the e-prescribing standards. For example, issues surrounding the use of e-prescription data for legitimate research activities should be resolved well before the system is operational.

**COMMENT 13: USE OF FORMAL RULEMAKING IN THE DEVELOPMENT PROCESS**
**(Responds to BACKGROUND, Section F)**

CMS states in the Proposed Rule that "[f]inal standards are standards that would be adopted in regulations through the rulemaking process," and include standards adopted through pilot testing as well as those for which CMS determines pilot testing is unnecessary.[15] We understand this statement to mean that CMS will adopt all final e-prescribing standards through notice and comment rulemaking, consistent with its approach to establishing the foundation standards.

We strongly support this approach. In addition to being consistent with the e-prescribing provisions of the MMA and rulemaking requirements under the Administrative Procedure Act (APA), adopting e-prescribing standards through notice and comment rulemaking will allow for robust input from all stakeholders in the health care system, thereby maximizing the potential for a successful e-prescribing program.[16]

We also recommend that CMS use notice and comment rulemaking to develop the initial standards for pilot testing. Because pilot testing is necessary for any standard (other than those for which there is "adequate industry experience"[17]) to become a final standard, the selection of standards for pilot testing is of critical importance. CMS therefore should ensure that all interested parties have ample opportunity to suggest standards for pilot testing and to comment on those that CMS itself proposes. In addition, a description of the results of the pilot testing (and CMS' interpretation of those results) should be publicly available when CMS elicits comments on the rules that would finalize the e-prescribing standards.

Finally, we recommend that CMS use notice and comment rulemaking to determine whether there is "adequate industry experience" for a standard such that pilot testing is unnecessary. This would ensure that all participants in the

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[15] 70 Fed. Reg. 6258.

[16] *See* SSA § 1860D-4(e)(3)(A) (providing that CMS "shall provide . . . for the promulgation of uniform standards relating to the requirements for electronic prescription drug programs") (emphasis added); § 1860D-4(e)(4)(D) ("[b]ased upon the evaluation of the pilot project . . . , [CMS] shall promulgate uniform [e-prescribing] standards") (emphasis added).

[17] *See* SSA § 1860D-4(e)(4)(C)(ii).

health care system have an opportunity to provide CMS with their assessment of the degree to which standards have been adopted, and thus foster sound determinations concerning where pilot testing is appropriate.

## COMMENT 14: UPDATING STANDARDS WITHOUT FORMAL RULEMAKING

**(Responds to BACKGROUND, Section F)**

In the Proposed Rule, CMS states that it will adopt updated versions of e-prescribing standards by publishing a notice in the Federal Register incorporating the updated standards by reference.[18] CMS indicates it will use notice and comment rulemaking to update e-prescribing standards where "the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction."[19] CMS states that it would "consider waiving" notice and comment rulemaking where updates or newer versions of a standard do one of the following:

1. "correct technical errors";
2. "eliminate technical inconsistencies"; or
3. "add functions unnecessary for the specified e-prescribing transaction."[20]

We agree that under certain circumstances, it might be "unnecessary" and "contrary to the public interest" to delay adoption of e-prescribing standard updates to allow for prior notice and comment.[21] We offer the following recommendations to ensure that the regulatory update process comports with the APA and ensures appropriate stakeholder input.

First, rather than the three categories specified above, CMS should provide that notice and comment rulemaking would be waived only for updates that CMS determines will not impose a material new compliance burden for regulated entities. Because the subject of e-prescribing standards is inherently "technical," it may not be particularly useful to focus on assessing whether updates to standards "simply correct technical errors or eliminate technical inconsistencies."[22] It is possible for updates seemingly making only "technical"

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[18] 70 Fed. Reg. 6267.

[19] *Id.*

[20] *Id.* CMS further states that "in the later case" (which we presume to refer to cases where an update adds functions unnecessary for the transaction), it "likely" would adopt both the previous standard and the new standard, so that adherence with either version would constitute compliance with the standard.

[21] 5 U.S.C. § 553(b)(B) (providing that notice and comment rulemaking may be waived where an agency for "good cause" finds that notice and comment would be "impracticable, unnecessary, or contrary to the public interest," and sets forth such finding in the rule).

[22] *Id.*

changes to entail material compliance burden for plans and providers, and thus to necessitate public comment prior to their adoption.[23] Therefore, it is more appropriate to focus on determining the likelihood of an updated standard imposing new obligations on regulated entities, rather than on whether the update makes "technical" changes or corrections.[24]

Second, CMS should specify that any updates or revisions not subject to prior notice and public comment will be adopted through an interim final rule with comment. CMS's determination that an update or revision does not impose material new compliance burdens should be sufficient to enable the agency to adopt the update without prior public comment. In order for the updated standard to be binding, however, it would need to be adopted through an interim final rule or other "legislative" rule.[25]

Moreover, the interim final rule process would provide an important safeguard in situations where CMS underestimates the impact of an update on the regulated community, or otherwise mistakenly assumes it to be small or uncontroversial. Similarly, it would give stakeholders an opportunity to submit comments advising CMS of a lack of industry experience with an updated standard that would call for pilot testing.[26] An interim final rule that contains a clear explanation (as required under section 5 USC § 553(b)(B)) of why CMS believes the update should not be subject to prior notice and comment, and a subsequent public comment period for stakeholders to respond to this determination, would ensure that CMS has the benefit of input from the full range of parties who would be affected by the adoption of the updated or revised e-prescribing standard.[27]

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[23] *See, e.g.*, Hemp Industries Ass'n v. DEA, 333 F.3d 1082, 1087 (9th Cir. 2003) ("Legislative rules . . . create rights, impose obligations, or effect a change in existing law pursuant to authority delegated by Congress," and "[a]n agency can issue a legislative rule only by using the notice and comment procedure described in the APA, unless it publishes a specific finding of good cause documenting why such procedures 'are impracticable, unnecessary, or contrary to the public interest'") (emphasis added).

[24] Under this approach, it would still be appropriate for CMS to forgo prior notice and comment rulemaking when it adopts both an updated standard that does not add new functions necessary for the transaction as well as the prior adopted standard with which the updated standard is "backward compatible." *See* 70 Fed. Reg. 6267. Under such circumstances, no new compliance burden would be established, because the prior adopted standard could still be used to comply with the e-prescribing regulations.

[25] *See, e.g.*, General Electric Co. v. EPA, 290 F.3d 377, 382-83 (D.C. Cir. 2002) ("If a document expresses a change in substantive law or policy . . . which the agency intends to make binding, or administers with binding effect, the agency . . . must observe the APA's legislative rulemaking process").

[26] *See* SSA § 1860D-4(e)(4)(C)(ii).

[27] We also note that, according to the Proposed Rule, it appears CMS will specify each e-prescribing standard (including version number and date of adoption) in the text of the regulations. *See* 70 Fed. Reg. 6273-74 (proposed 42 C.F.R. § 423.160(b), (c)). It does not appear that changes to this regulatory text to reflect the adoption of new versions of the standards (which CMS appropriately would establish via a legislative rule through notice and comment) could be made except by another legislative rule, such as an interim final rule or prior

## Summary of Recommendations

The major recommendations made in these comments may be summarized as follows.

1. Consistently request a coherent set of design principles to develop system standards

   - Design the system to improve patient care and strengthen the physician-patient relationship by putting the patient first, protecting patient privacy, promoting physician-patient communication, and protecting the physician's role.
   - Provide information needed by prescribers (and information needed to protect beneficiaries) at the point of care. Ensure that the system can work with other electronic health information systems to obtain this information.
   - Reduce the overall cost of care and provide value to all parties using the system.
   - Cover the entire prescribing process.

2. Do not focus exclusively on information content. When appropriate, standards should also regulate the integrity and display of this information.

3. When assessing the system's value, consider its impact on all aspects of health care costs, and the extent to which it actually is accepted and used.

4. Retain and strengthen the current criteria for "adequate industry experience."

5. Drop the "Formulary Alternatives List" from the proposed NCPDP Formulary and Benefit Standard.

6. All steps in prior authorization should take place through the e-prescription system, at the point of care.

7. Drug information should match the structured product label (SPL) in content and format. Any additional information should satisfy the standards developed for e-prescription messages.

8. Standards for e-prescription messages should be developed before messages are allowed (even during pilot testing).

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notice and comment rulemaking. *See, e.g.*, Hemp, 333 F.3d at 1088 ("only legislative rules (*i.e.* rules having the force of law) can amend a prior legislative rule"); Erringer v. Thompson, 371 F.3d 625, 632 (9th Cir. 2004) ("Any rule that effectively amends a prior legislative rule is legislative and must be promulgated under notice and comment rulemaking").

9. Rely on SPL and formulary information, along with symbols indicating when AB-rated generics are available, to help prescribers to identify lower cost therapeutically appropriate alternatives.

10. Establish an infrastructure for the development process that enables all stakeholders to play a meaningful role.

    - Create and publicize a blueprint for the system.
    - Provide clear and consistent guidance.
    - Engage all stakeholders.
    - Promote pilot-testing.
    - Be proactive about identifying and resolving issues concerning other laws and requirements administered by CMS or HHS.

11. Adopt all final standards through formal rulemaking, including an opportunity for notice and comment. Updated versions of the final standards that do not impose a material new compliance burden may be adopted through an interim final rule with opportunity to comment.

We appreciate the work that will go into developing standards for the e-prescription system in response to the public's comments. We are confident that the resulting system will work well to achieve its objectives of improved access to affordable medicines. If you have any questions or we may be of further assistance, please feel free to call either of the undersigned at 202-835-3400.

Sincerely,

Richard I. Smith
Senior Vice President
Policy, Research &
Strategic Planning

Bruce Kuhlik
Senior Vice President
& General Counsel
Legal Department

Attachment

## Appendix

### Points from the Discussion of Commercial Messaging before and by the National Committee on Vital and Health Statistics (NCVHS)

***From the NCVHS letter to the Secretary of Health and Human Services (HHS), September 2, 2004.***

> **Observation 15 (Policies to Remove Barriers):** Testimony identified widespread industry concerns relating to safe harbor, preservation of provider/patient choice, and freedom from commercial bias in messages received through e-prescribing applications.
>
> Recommended Action 15.1: HHS should ensure that regulations define the parameters of safe harbor, ensure preservation of provider/patient choice, and require that e-prescribing messages received through e-prescribing applications be free from commercial bias.

***From the Deliberations of the NCVHS Subcommittee on Standards and Security, July 29, 2004***

- "In the testimony about level playing field, neutral presentation, you are going to put six drugs on a screen what is neutral to you? Is it alphabetical? I am serious. It is a good philosophy but give me a reality shot." *Harry Reynolds, BCBS North Carolina*
- "I sort of see [commercial messaging] as like a HIPAA issue, which is, it is part of regs. It is a complete driven process and if users are beginning to feel that there is too much commercial information coming down then it is something that CMS has to investigate." *Simon Cohn, MD, Kaiser (Subcommittee Chair)*
- "The concern about having commercial messages pop up (during) prescribing is not, in my mind, a standards issue. It is an issue related to the software application ... or the network vendor. That does not mean that I don't think it is important because from what we just heard, if we are blind to the effects of these, it not only hurts the different pharmaceutical companies that may try to be ethical, but it could be a deterrent to the acceptance of e-prescribing. ... We have a category here of important related issues and I think that is where this goes." *Jeff Blair, Medical Records Institute*
- "I think all of us want to make sure that e-prescribing promotes health but we also don't want to do marketing, which is I think what you were all pointing to, and so the question that always gets to me is that the line here is not a sharp

line and I think we saw that with the privacy regulations also and I am just reflecting on that." *Simon Cohn, MD, Kaiser (Subcommittee Chair)*

- (With regard to recommendations for a "zone of autonomy" around prescribers) "My question is, sort of, who and how those things would be enforced. Who should make those policies, what process would you recommend and then how would they be enforced because some of these I think at least they are essentially describing the content that would allow it to flow. It wouldn't really change the format of the standard or the technology standard. So, it is almost like now we have to have some sort of censor or policeman or somebody who is looking at content trying to decide whether these, I am having a hard time; I am struggling a little. I like the principles but I am struggling with the implementation and how this would work." *Stan Huff, MD, Intermountain Healthcare, University of Utah*

PhRMA

# FAX

**Policy and Research Division**

1100 15th Street NW
Suite 900
Washington D.C. 20005

Date: 4/6/05

From:

| | |
|---|---|
| Rick Smith | (202) 835-3572 ☐ |
| Sharon Brigner | (202) 835-3489 ☐ |
| Randy Burkholder | (202) 835-3427 ☐ |
| Kathleen D'Amore | (202) 835-3543 ☐ |
| Nina DeLorenzo | (202) 835-3443 ☐ |
| Romy Gelb | (202) 835-3526 ☐ |
| Valerie Higgs | (202) 835-3513 ☐ |
| Ruth Hoffman | (202) 835-3498 ☐ |
| Tim Hrynick | (202) 835-3445 ☑ |
| Emily Johnson | (202) 835-3552 ☐ |
| Wendy Krasner | (202) 835-3578 ☐ |
| Tim McClung | (202) 835-3400 ☐ |
| Greg Portner | (202) 835-3551 ☐ |
| Erin Ravelette Flynn | (202) 835-3493 ☐ |
| Lori Reilly | (202) 835-3463 ☐ |
| Joe Reblando | (202) 835-3453 ☐ |
| Alex Shekhdar | (202) 835-3557 ☐ |
| Gretta Thorn | (202) 835-3531 ☐ |
| Jennifer Van Meter | (202) 835-3403 ☐ |

SENT PER MARIA FRIEDMAN'S INSTRUCTIONS. ORIGINAL COPY WAS DELIVERED TO HHS MAILROOM ON 4/4/05 BUT MAY HAVE BEEN MISDIRECTED.

PLEASE CALL WITH ANY QUESTIONS.

Number of pages including cover sheet 2/0

To: LAURA GANGE

Phone: 410.786.6333

Fax: 410.786.1347

CC: _____

Division Phone: (202) 835-3543
Division Fax: (202) 835-3595

| REMARKS: | | | | | | | |
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Johnson & Johnson
HEALTH CARE SYSTEMS INC.

1125 Trenton-Harbourton Road
Titusville, NJ 08560

Michael Weinberger
*Executive Director, Prescribing Alliances*
*Managed Markets Division*

Phone: 609-730-3739
E-mail: mweinbe1@scaus.jnj.com

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April 5, 2005

**Hand Delivery**

The Honorable Mark B. McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–0011-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-0011-P; Medicare Program; E-Prescribing and the Prescription Drug Program**

Dear Dr. McClellan:

On behalf of Johnson & Johnson Health Care Systems, I am writing to comment on the Proposed Rule entitled "Medicare Program; E-Prescribing and the Prescription Drug Program," see 70 Fed Reg. 6,256 (Feb. 4, 2005) (the Proposed Rule). Johnson & Johnson Health Care Systems Inc. provides account management and customer support services to key health care customers, including hospital systems and group purchasing organizations, leading health plans, pharmacy benefit managers, and government health care institutions. The company also provides contract management, logistics and supply chain functions for the major Johnson & Johnson franchises.

Johnson & Johnson Health Care Systems appreciates this opportunity to comment on this Proposed Rule and looks forward to working with CMS to ensure that e-prescribing is implemented in a manner that optimizes clinical standards of care and superior patient outcomes.

## I. Johnson & Johnson Supports Electronic Prescribing

Johnson & Johnson Health Care Systems is a strong proponent of electronic prescribing. While proper studies are needed, we have every reason to believe that e-prescribing will result in fewer medication errors, improved process and cost efficiency, and better patient therapeutic compliance. We have also noted the observations made by many in the healthcare technology field that e-prescribing is a first step toward the broader adoption of electronic medical records and the electronic interchange of pertinent information between interoperable provider healthcare systems. While we support the principle of electronic prescribing, we want to ensure that, in moving quickly to realize its unique benefits, we do not inadvertently compromise a physician's ability to exercise his or her best clinical judgment to the detriment of patient care.

### A. We Support CMS's Efforts to Identify and Evaluate Industry Experience with the Proposed Technical Standards; Standards for "Prescription-related Information" Should Not be Finalized without Adequate Pilot Testing

The Proposed Rule does an excellent job addressing the technical standards necessary to move prescription information "from Point A to Point B," and we support the agency's criteria for evaluating industry experience with these standards. Specifically, we agree that ANSI accreditation is an important indicator of industry experience. As noted in the Proposed Rule, the ANSI accreditation process is accessible to all interested stakeholders. See 70 Fed. Reg. at 6,261. Consequently, this process promotes broader industry participation and greater familiarity with these standards, which in turn increases the prospect that any final standards will address and be responsive to industry needs.

We also support the requirement that any e-prescribing standard must have been implemented by those entities that will be subject to the electronic prescribing requirements and should be recognized by key stakeholders as an industry standard. See id. Industry implementation is crucial to ensuring that any proposed standard will be capable of operating in the real world. Similarly, broad industry recognition is important to ensure that the standard is commercially viable, and not simply one of many "standards" currently in use that may not survive if the industry ultimately selects a single standard.

We agree with CMS that the industry has sufficient experience with the NCPDP SCRIPT and Telecommunication standards and the X12N 270/271 standard to warrant immediate adoption as foundation standards. We are not as confident about industry experience with those proposed elements of the technical standards regarding the transmittal of "prescription-related information" that is, formulary information, medical history, and medication history. Even if these can quickly become ANSI accredited, industry still lacks the same significant hands-on experience it has had with the other foundation standards. Therefore, as described below, we believe that these, and indeed all future standards, should be subject to (and not accepted as final without) the pilot testing provided for in the Medicare Modernization Act (MMA) and the Proposed Rule. See 42 U.S.C. § 1395w-104(e); 70 Fed. Reg. at 6,228, 6,261.

## B. We Encourage CMS to Utilize the Pilot Testing Program to Assess Future E-prescribing Standards

Pilot testing of future e-prescribing standards, including formulary information, medical history, and medication history standards, is crucial to ensuring that they will function in a manner that enhances the prescribing process without placing an undue burden on users. For example, pilot testing will enable the agency to determine whether

standards that work in a closed system, among a relatively small number of stakeholders, remain effective in a larger, more open environment, or whether standards that operate flawlessly in isolation become problematic when combined with other standards. Pilot testing these standards is the only means for identifying and addressing these issues as they arise in a real-world environment. As a result, we believe that all future e-prescribing standards must be subjected to pilot testing to help ensure the program functions as Congress intended.

In addition to evaluating the real-world functionality of technical standards, pilot testing is also crucial to assessing certain concerns not addressed in the Proposed Rule, namely those process standards that are necessary to ensure that e-prescribing does not interfere with physician prescribing practices. In this regard, in the MMA and its accompanying Conference Report, Congress identified several areas of concern in the e-prescribing program, specifically prohibiting inappropriate messaging and indicating that physicians should have unbiased access to the full range of prescribing information. See 42 U.S.C. § 1395w-104(e)(3)(D); H.R. Conf. Rep. No. 108-391, at 455. Nevertheless, the Proposed Rule contains virtually no discussion of these issues. See, e.g., 70 Fed. Reg. at 6,262. These process standards are discussed in greater detail below.

## II. Process Standards: Enhancing the Rule to Set Standards for the Operational Characteristics of the Interface in Addition to "Technical Standards"

As mentioned above, the Proposed Rule focuses on the technical standards needed to transmit information. However, we believe that the MMA contemplated, in addition to technical standards, governance of how software programs interact prescribers. On March 1, 2005 CMS held an Open Door Forum on electronic prescribing. At that meeting, several parties including Johnson & Johnson Health Care Systems, commented on the value of establishing not only standards for the technical transmission of prescription information but also "process standards."

Process standards are those standards that ensure fairness in the prescribing process used by an e-prescribing system. They apply to the actual act of electronic prescribing; the manner in which information is presented to prescribers and the way in which systems interact with those prescribers. The intent of Congress, as seen in the MMA and its accompanying Conference Report, is that e-prescribing standards would ensure that e-prescribing systems function in a fair, transparent, and unbiased manner. Specifically, the MMA requires that e-prescribing "allow for the messaging of information only if it relates to the appropriate prescribing of drugs," and the Conference Report states that prescribers must have access to "neutral and unbiased information on the full range of covered outpatient drugs." 42 U.S.C. § 3195w-104(e)(3)(D); H.R. Conf. Rep. No. 108-391, at 455-56. The Conference Report further states that Congress did not intend for e-prescribing "to be used as a marketing platform **or other mechanism to unduly influence the clinical decisions of physicians**." Id. (emphasis added).

It is this underlined passage that we believe indicates the need for CMS to implement process standards for the user interface. We are concerned that, absent such standards, the potential exists that this technological opportunity will be abused. Consequently, we believe that it is important that the regulations include safeguards to proscribe inappropriate messaging that is aimed at influencing the prescribing decision.

### A. The Most Likely Location for Misuse: The User Interface

In particular, we believe that "neutral and unbiased" presentation covers not just the information itself, but the way in which the display of that information could be manipulated to drive particular behaviors. We believe that, when a physician prescribes a drug, he or she should be presented with all pertinent information at the beginning of the prescribing process, including a single, consolidated list of appropriate drugs. This list should indicate which drugs are on-formulary preferred, on-formulary but not preferred,

and entirely off-formulary. The listed information should be provided on a single (and if necessary scrollable) screen without the need for excessive "clicking" or burdensome navigation. Presenting this information in any other manner might constitute an attempt to unduly influence the physician's selection before he or she has been fully informed of the complete range of choices and may make it less likely that the physician will see the names of drugs that may offer better efficacy and tolerability for the patient, but are not as incentive- and rebate-friendly. We strongly believe that, under the best standard of care, a physician and patient should be given full exposure to all clinical and financial information related to a prescription prior to a therapeutic decision being made. The regulations should promulgate process standards that expressly incorporate these protections.

**B. Inappropriate Messaging Should be Clearly Defined**

As noted above, the MMA clearly proscribes inappropriate messaging. See 42 U.S.C. § 1395w-104(e)(3)(D). It is our position that such messaging must be understood to include not just commercial advertising, but any kind of messaging via the interface, the intent of which is to effect a change in the prescription without respect to clinical factors. We are not suggesting that physicians should not be made privy to financial information such as formulary status and cost to the patient. To the contrary, physicians clearly should have this information. However, they should receive such information up front, before making the prescribing decision. We believe that messages that are triggered by non-clinical aspects of the prescription could be used to make the prescribing experience burdensome or inconvenient until the physician ultimately submits to changing the prescription despite his or her clinical opinion on what is the best treatment for the patient. The agency should promulgate process standards that prohibit this inappropriate messaging.

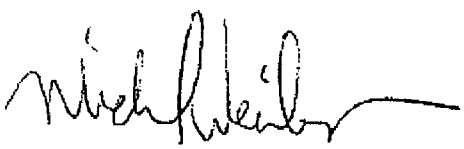
### C. Prohibiting Inappropriate Financial Incentives

We believe that in order to satisfy the clear intent of Congress that the prescribing process be unbiased and objective, the regulations should not permit plans, PBMs, or other entities to pay vendors engaged in the electronic prescribing process based on which drugs are prescribed. Thus, these entities should not be permitted to pay these vendors a "bounty" for each prescription they successfully switch from the physician's intended selection to a more rebate-friendly or otherwise financially appealing choice that does not specifically consider the best care of a particular patient. While, in some instances, the preferred formulary drug may achieve the best balance of clinical and financial value for the patient, in other cases, there may be drugs that are on-formulary but not preferred, or are off-formulary, which better serve the patient's needs. In these instances, the physician should not be subjected to interruptive pop-up messages that attempt to persuade him or her to select a certain drug because it is financially more attractive to certain stakeholders (e.g., due to higher rebates or incentive payments).

## III. Conclusion

We appreciate the opportunity to comment on these important electronic prescribing issues raised by the Proposed Rule. We would be happy to provide additional information to you or your staff on the topics we have addressed in this letter.

Sincerely,



Michael Weinberger

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PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

PCMA



April 5, 2005

The Honorable Mark McClellan, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: File code CMS-0011-P

Dear Dr. McClellan:

On behalf of America's pharmacy benefit managers (PBMs), the Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments on the proposed rule to adopt standards for an electronic prescription drug program for the Medicare Part D program.

PCMA commends the Centers for Medicare & Medicaid Services (CMS) for recognizing that electronic prescribing provides the promise of improved patient safety, reduced health costs, and increased quality and efficiency of care for all Medicare beneficiaries. We also recognize the National Committee on Vital and Health Statistics (NCVHS) in developing the proposed standards in such a tight timeframe.

PCMA would like to summarize our position in the following points:

***E-prescribing is key to patient safety***.

- Of patients who received at least one prescription, 25% reported an adverse drug event and 39% of these events were preventable.
- Complete patient medication history made available through e-prescribing would help identify potential adverse drug interactions.
- E-prescribing avoids complications associated with illegible, hand-written prescriptions.

***E-prescribing can result in huge cost savings.***

- Access to formulary information (such as lower-cost generics and co-pay information) at the point of prescribing can ensure appropriate care while reducing expenditures.

***PBMs are at the forefront of e-prescribing***.

- An infrastructure that connects payers, physicians and pharmacies is key to the effective utilization of e-prescribing systems. PBMs already utilize such a system.

***National uniform standards are necessary to make e-prescribing work***.

- A patchwork of state standards will create barriers to adoption of e-prescribing by prescribers, pharmacists and payors in Medicare and the commercial sector.

In the 2004 eHealth initiative report titled "*Electronic Prescribing: Toward Maximum Value and Rapid Adoption*" it is stated that Americans made more then 823 million visits to physicians' offices in 2000 and, according to the National Association of Chain Drug Stores (NACDS), four out of five patients who visit a doctor leave with at least one prescription. More than 3 billion prescriptions are written, and prescription medications are used by 65 percent of the U.S. public in a given year. The study goes on to state that 25 percent of patients who received at least one prescription reported an adverse drug event, and 39 percent of these events were deemed either ameliorable or preventable.

Electronic prescribing can help prevent medication errors because it instantly links the health care provider, the pharmacy, and the payers. Patient medication history and insurance information can be available for the physician when prescribing and, at the pharmacy, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication. Patient safety can also be improved through avoiding hard-to-read physician handwriting and by automating the process for determining drug interactions and allergies.

E-prescribing can also improve efficiency and reduce costs by providing information about the formulary, including lower cost generics, and co-pay information. It can help make sure that patients and health professionals have the best and latest medical information at hand when they make important decisions about medicines, helping patients get the most benefits at the lowest cost. In addition, e-prescribing shows promise in creating efficiencies in the physician's office and the pharmacy. This can be done by reducing the costs associated with patient eligibility checks and creating timely interfaces with formularies to make sure the correct drug is prescribed the first time.

## State Preemption
## [Background, A. Statutory Basis, H. Summary of Status of Standards for an Electronic Prescription Drug Program]

PCMA is concerned with the limited manner in which CMS has interpreted its preemption authority. We recommend that CMS revise the limited interpretation of preemption to ensure the federal standards fully preempt any state law or regulation that affects e-prescribing. We believe the clear intent of Congress was to limit the barriers of physician and pharmacist adoption of e-prescribing and provided CMS with the authority necessary to ensure a single national standard.

PCMA believes that creating unified e-prescribing standards through appropriate and full preemption of state laws is a critical component to the ultimate success of e-prescribing. State laws and regulations, if they deal with e-prescribing, tend to make the e-prescribing process less efficient, or even illegal, and therefore not likely to be utilized by payors, physicians and pharmacists. The National Association of Boards of Pharmacy (NABP) model act, states that electronic prescriptions must be transmitted directly to the pharmacy "with no intervening person or third party having access to the prescription drug order". For those states that have adopted this language, this would mean that electronic prescriptions that convey any formulary information or comprehensive medication history would not be allowed.

With the increased attention on the value information technology (IT) can provide the health care system, policymakers are becoming more familiar with the barriers that exist to broad health IT adoption. An often noted barrier to adoption is the possibility of numerous, disjointed standards that directly impact how these systems will work in the practice setting.

In fact, the Department of Health and Human Services (HHS) press release in announcing the release of this proposed rule stated, "The current lack of common standards is a barrier to the use of health information technology, including e-prescribing."[1] Also, in the HHS Goals for a Strategic Framework for Health IT adoption said "the government has made a commitment to using common standards and architecture...The result will be a more cost-effective and efficient healthcare system."[2]

The GAO has identified in its 2004 report, "HHS Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption," specific barriers to adopting Health IT include financial, technical, and cultural aspects. Technical barriers, including a "lack of uniform standards for data submission and reporting" clearly show that a uniform standard is critical for the federal government to reduce or eliminate as many barriers to adoption as possible.

Despite a consistent call for uniform standards, the preemption interpretation in the NPRM creates a system that enables numerous and differing standards which subsequently creates barriers to adoption by prescribers, pharmacists, and payors. Under the interpretation of preemption within the NPRM it is possible to have differing Medicare e-prescribing standards in each state, even if that state is combined in a single PDP or MA region

***NPRM, p. 6258- Adopted Medicare standards must create a conflict for a state law to be preempted.***

***Comment- PCMA disagrees with this interpretation and recommends CMS reverse this interpretation.***

It is of particular importance that under no circumstance should an individual state e-prescribing standard apply to the Medicare program even in situations where Medicare has not formally adopted a specific e-prescribing standard. There are aspects of e-prescribing contemplated in the statute that are beyond the traditional regulation of practicing pharmacy and directly relate to benefit and plan design where state pharmacy laws should not have jurisdiction.

The Medicare established e-prescribing standards should be adopted in a manner that does not require a standard-by-standard evaluation to determine which individual state standard may or may not be preempted. This would create a burdensome review to compare the Medicare

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[1] "E-prescribing proposed rule," Department of Health and Human Services-Press Release.

[2] "Goals of Strategic Framework." Department of Health and Human Services, Office of the National Coordinator for Health Information Technology (ONCHIT);

e-prescribing standards and that of each relevant state law and regulation to determine where Medicare has created a standard and where it has not.

Preemption is also addressed in Sec. 1860-D-12(g), which CMS has interpreted to apply to all state laws "except licensure and solvency."

This limited interpretation of preemption would be contrary to the intent of two provisions in the statute by applying e-prescribing standards to Medicare (besides those established under Part D) and creating administrative burden on prescriber and pharmacist obligations.

First, the statute states in Sec. 1860D-4(e):

> "...prescriptions and other information described in paragraph (2)(A) for covered Part D drugs prescribed for part D eligible individuals that are transmitted electronically shall be transmitted only in accordance with such standards under an electronic prescription drug program that meets the requirements of paragraph (2)." [underline added]
>
> In addition, the Conference Agreement also states:
>
> "The [e-prescribing] standards apply to prescriptions for covered part D drugs and required information that are transmitted electronically under an electronic prescription drug program conducted by a PDP or MA plan."[3]

While Congress did not require prescribers to use e-prescribing, this section demonstrates—1) the intent that any electronic prescribing that occurs in Medicare will follow the Medicare standards and 2) that these standards would apply to any e-prescribing program conducted by a PDP or MA plan. This would include any part of Medicare, including Part A, B, C or D.

Second, the statutory language at Sec. 1860D-4(e)(3)(C)(i) states:

> "standards be designed so that, to the extent practicable, they do not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists."

With the potential of having to determine which state standard or Medicare standard applies in a variety of known and unknown situations, prescribers and pharmacies will experience enormous burden to carry out Medicare e-prescribing. In fact, situations would exist that performing Medicare e-prescribing would actually violate state prescribing laws.

***NPRM, p.6258-6259- Preemption is limited only to the Part D program.***

***Comment- PCMA disagrees and recommends CMS interpret preemption to apply broadly to state laws and regulations beyond Medicare.***

---

[3] Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Agreement. p.23

We believe CMS has the authority necessary to govern all electronic prescription of any drugs included in the Part D program, so as to ensure a single, national electronic prescription drug program that would be adopted and used consistently by prescribers to the benefit of Medicare and the rest of the health care system.

Examples of state e-prescribing laws or regulations that are burdensome include: requiring a fax or hard copy to follow an e-prescription, prohibiting specific scheduled drugs, and prohibiting interstate transmission of prescriptions.

With a large focus of resources and time needed by all partners in the e-prescribing systems to overcome the obvious challenges of prescriber start up costs and broad education about the value proposition of e-prescribing, it is critical that the standards and processes that make the technology function not add to this formidable challenge.

## Stark Anti-kickback
## [A. Statutory Basis, 3.Anti-kickback Safe Harbor and Stark Exception]

***Comment:***

We look forward to reviewing and commenting on the impending OIG NPRM relating to this safe harbor. PCMA believes it is critical that incentives be allowed to be offered to providers by PDPs, PBMs, and health plans to encourage provider adoption of e-prescribing.

## Foundation standards
## [F. Evolution and Implementation of an Electronic Prescription Drug Program]

***Formulary and Medication History Information***

***Comment:***

PCMA recommends that the Rx HUB standards for formulary and benefit information be considered to have sufficient industry experience and therefore included as foundation standards. We do not believe it is necessary for ANSI accreditation to demonstrate sufficient industry experience. For a meaningful e-prescribing system, it is critical that formulary information and medication history be included as soon as practical. These two functions provide the backbone for the ultimate goals of e-prescribing—increasing patient safety and reducing cost.

While there is value in the ANSI accreditation process, CMS should not require ANSI accreditation of e-prescribing standards to be included as foundation standards. The Rx HUB standards are in operation today by the three largest pharmacy benefit managers (PBMs) and no other alternative exists today. In addition, the possibility exists that the ANSI accreditation process would be slowed down by those who may not favor expedient adoption with no alternative approach.

*ASC X12N 270/271*

***Comment:***

We support the naming of the ASC X12N 270/271 transaction set as a "foundation standard" for the MMA e-prescribing program. The ASC X12N 270/271 is currently in widespread use for checking eligibility and is used in a manner compliant with the HIPAA privacy regulations between prescriber and pharmacy benefit managers/payers.

We understand that there is not much (if any) industry experience in using the Eligibility Verification (Transaction Code E1) NCPDP Telecommunication Standard for Health Care Claims as an eligibility inquiry from the dispenser to the payor. In addition, the E1 message is not designed to handle multiple coverage (COB) responses, as it is only designed to handle verification of a patient's cardholder status for a specific benefit program. Given that this transaction has little relevance in electronic prescribing and is not being used, we recommend that it be excluded from the final rule. At minimum, we recommend that this transaction be piloted and appropriately modified before being named as a foundation standard for eligibility inquiry and response.

***National Provider Identifier (NPI)***

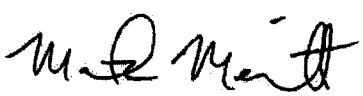
***Comment:***

PCMA supports the goal of having a single system for identifying providers and the long term solution of using the identifier for all transactions that require one. However, the current timeframe for implementing the NPI should not be altered, and any temporary solution should look to current industry practice until the NPI is fully implemented.

CMS should make use of identifiers that are currently available and in use such as the NCPDP Provider Indentifier Number. This identifier should be adopted for electronic prescribing until the NPI is fully in place. Any other approach will create significant inefficiencies by forcing the industry to change processes and adapt something new, only to make additional changes when the NPI is implemented a short time after.

PCMA is committed to continue working with HHS, CMS and all relevant stakeholders to realize a national e-prescribing solution that will improve patient safety, limit administrative burdens on prescribers, and reduce costs for the Medicare program as well as the commercial sector.

Sincerely,



Mark Merritt

#8 81

American Academy of Dermatology Association

1350 I St NW Ste 870
Washington DC 20005-3319
**Phone** 202/842-3555
**Fax** 202/842-4355
**Web Site** www.aad.org

**Clay J. Cockerell, MD**
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April 5, 2004

Mark B. McClellan, MD, PhD, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

RE: Proposed Rule: Medicare Program; E-Prescribing and the Prescription Drug Program – CMS-0011-P

Dear Dr. McClellan:

On behalf of the 14,000 members of the American Academy of Dermatology Association, I appreciate this opportunity to comment on the proposed rule for electronic prescribing (e-prescribing) standards. These standards represent another important step on the road to developing, promoting, and integrating a national health information technology network for healthcare professionals to provide safe, quality-based, efficient and affordable patient care.

As office-based physicians, dermatologists recognize e-prescribing is as much a patient safety issue as it is a workflow issue. Indeed, the most apparent benefits for dermatologists using e-prescribing include: speedy point-to-point ordering, transmission and tracking from physician prescribers to dispensing pharmacies; reduced medication errors or duplication; increased accuracy and transparency of the transaction; improved legibility; efficiency gains in practice workflow and reduced administrative steps; as well as enhanced ability to share and coordinate patient care information.

To achieve and maintain these benefits we feel that the proposed federal e-prescribing standards should allow for the operational flexibility and scalability for the prescribing physicians. This would facilitate appropriate management of prescription volume and medication options, especially in ambulatory practices. Furthermore, we urge that the initial e-prescribing standards adopted for the 2006 test pilot project be designed to include the full participation of office-based specialists, including dermatologists, in both rural and urban settings in order to identify and mitigate against any potential health information technology divide and socio-economic disparity that may compromise the quality, safety, and efficiency in the delivery of patient care. Effectively, the results from proposed e-prescribing pilot testing should help address the need for physicians in small and medium-sized ambulatory practices to adopt uniform, user-friendly, and interoperable standards for the provision of safe, quality-based care.

The proposed federal standards should take into account, and promote the elimination of, prevailing barriers to adoption and usage most common among small and medium-size dermatology practices. These barriers include:

- Cost of purchasing and implementing such a system;
- Lack of interoperable capabilities between healthcare professionals to ensure effective coordination of care;
- Complex and user-unfriendly health information technology that offsets any benefits related to administering quality of care;
- Lack of reliable systems' interface with existing practice systems; and
- Lack of financial incentives for the small business provider;

These significant disincentives need to be addressed and these current obstacles removed in order to promote adoption and implementation by physicians.

The Academy is confident that e-prescribing can help advance safe, quality-based, efficient and affordable patient care; therefore further consideration must be given to overcoming the above structural, operational and fiscal barriers. Healthcare electronic processes can be beneficial for both patients and physicians and e-prescribing is another step in the right direction.

Thank you for reviewing these comments. If you have any questions regarding our recommendations, please contact Jayna Bonfini at jbonfini@aad.org at 202-712-2614, or William Brady at wbrady@aad.org or 847-240-1824.

Sincerely,

Brett Coldiron, MD, FACP
Chair/AAD Health Care Finance Committee

Cc: Clay J. Cockerell, MD, President, AADA
Stephen P. Stone, MD, President-Elect, AADA
David M. Pariser, MD, Secretary-Treasurer, AADA
Ronald A. Henrichs, CAE, Executive Director and CEO, AADA
John D. Barnes, Deputy Executive Director, AADA
Judith Magel, Director, Health Policy and Practice, AADA
Laura Saul Edwards, Director, Federal Affairs, AADA
Cyndi Del Boccio, Director, Executive Office, AADA
Norma Border, Senior Manager, Coding and Reimbursement, AADA
Jayna Bonfini, Manager, Political Affairs, AADA
William Brady, Manager, Practice Management, AADA

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

April 1, 2005

Mark McClellan, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

**Re: Comments on the Medicare Program: E-Prescribing and the Prescription Drug Program Proposed Rule (42 CFR 423).**

Dear Dr. McClellan:

The American College of Physicians (ACP), representing over 116,000 doctors of internal medicine and medical students, is pleased to submit comments on proposed rule 42 CFR 423 --- "Medicare Program: E-prescribing and the Prescription Drug Program." ACP is well aware of the outstanding potential of e-prescribing to benefit the health of Medicare beneficiaries, and ultimately all Americans, in terms of reduced medication errors, improved quality of care, enhanced administrative efficiencies and lower costs. We are requesting your attention to the following issues to help ensure effective implementation of e-prescribing within the Medicare program.

1. The proposed prescription and eligibility/benefit electronic communication "foundation" standards.

The ACP supports your proposed implementation as "foundation" standards the NCPDP SCRIPT standard for prescription communications, the ASC X12N 270/271 Transaction standard for eligibility transactions between providers/institutions and health plans or just between health plans, and the NCPDP Telecommunication Standard for conducting eligibility transactions between dispensers and Part D sponsors. Each of these standards is already in widespread use in the industry both as individual standards and in combination and are recognized by the primary stakeholders within the e-prescribing field.

2. The inclusion of formulary representation and medication history standards in the final rule.

The proposed rule states the Centers for Medicare and Medicaid Services' (CMS') intention to adopt, as foundation standards in the final rule, formulary representation and

medication history standards, if certain characteristics are met and there is adequate industry experience with the standards. While we support the defined decision criteria, we strongly recommend the additional criterion of evidence that the standard successfully interacts with the other foundation standards. It is our opinion that such evidence is lacking and that pilot testing is necessary to ensure the usefulness and correctness of the standard.

3. The need to facilitate the rapid development of RxNorm and SPL structured terminology.

The College encourages CMS to expedite the development, pilot testing and implementation of the RxNorm terminology and SPL document specification. This common dictionary and structure will allow for the e-pescribing system to adequately capture subscriber intent when bridging systems using disparate drug databases. In addition, it would allow for the addition of multiple clinical decision support features into the system that have the potential to reduce medical errors and improve quality of care.

4. The proposed rule would require most hospitals and other large clinical settings to change their current prescription transmission standard.

HL 7 is the prescription transmission standard currently used by a predominance of hospitals and other large care delivery organizations. These facilities often require the complex/detailed prescription messages available with HL7, and not currently available through the NCPDP Script standard. These facilities would have to develop and support, at some substantial expense, NCPDP Script standard for prescriptions ordered under the Medicare Part D program under the current proposed rule. The College recommends that CMS address this issue and explore the possibility of changes to the proposed rule that would allow both HL7 and NCPDP Script specifications for prescription transactions. For example, the proposed rule could be modified to support the use of an intermediary that may be a different enterprise than the prescriber in translating HL7 pharmacy order messages to the required NCPDP format. The Cleveland Clinic Foundation has already demonstrated the feasibility of this approach.

ACP also requests that CMS address the more general issue of harmonizing e-prescribing communications between the hospital and outpatient settings. For example, a medication list provided by an outpatient setting should be able to inform the admission inpatient orders; and the inpatient order list should inform the outpatient medication list at the time of discharge.

5. The use of the HIPAA electronic transmission definition to define providers covered by the proposed rule will add inefficiencies and a significant financial burden to most providers employing electronic health record (EHR) systems.

Currently, most providers using an EHR system electronically fax prescriptions to patients' pharmacists. These providers would fall under the proposed e-prescribing rule based upon the HIPAA electronic transmission definition, which includes medical

information faxed from a computer. This is despite the fact that these EHR systems are not typically integrated with a true e-prescribing system. Thus, many practitioners who use an EHR system will be forced to implement one or more of the following to be in compliance with the proposed rule:

- Find an e-prescribing system consistent with the proposed rule to integrate into their current EHR system. Currently, the market only has a very limited number of e-prescribing systems capable of such integration. In addition, this adoption would add a significant financial burden to the practices.
- Revert to routinely providing patient's with paper prescriptions to take to the dispenser which adds both unnecessary costs and inefficiencies to the system.
- Create a new phone-based fax system to transmit prescriptions which adds both unnecessary costs and inefficiencies to the system. This means of faxing would be exempt from the proposed e-prescribing rule.

The College recommends that the electronic transmission definition used to define who is covered under the e-prescribing rule exclude computer-based fax transmissions.

6. The restrictive interpretation of language in the Medicare Modernization Act (MMA) that permits preemption of State laws for e-prescribing only within Medicare Part D.

The College supports the broadest interpretation of the State law preemption language included in the Medicare Modernization Act. The wide variation in State laws regarding electronic transmission of prescriptions imposes unnecessary complexity, substantial added costs and serves as a major barrier to the implementation and development of a truly functional national e-prescribing system.

ACP also requests some clarification regarding the interpretation of the State preemption language in the proposed rule. Will the current rule require physicians in those States that have laws in conflict with the adopted federal standard to follow two different protocols; one for prescription transmissions for Part D eligible and enrolled patients using the federal standard, and a second for prescription transmissions for all other patients that follow the State standard? If this is true, it basically eliminates one of the primary goals of e-prescribing, which is to increase practice efficiency.

7. The failure of the proposed rule to address how controlled drugs will be handled under the proposed Medicare e-prescribing system.

There is considerable variation among states regarding procedures physicians must follow when prescribing controlled substances. These variations interact with required Federal procedures. The situation is further complicated by the Federal Drug Administration (FDA's) current unwillingness to accept electronic signatures in prescriptions of controlled substances. ACP requests that CMS address the e-prescribing of controlled substances within the Medicare Part D program.

8. The issue of unique identifiers for dispensers, providers and patients.

ACP strongly supports the recommendation of the National Committee on Vital and Health Statistics (NCVHS), and the Department of Health and Human Services' (HHS') proposed intention of requiring the National Provider Identifier (NPI) for all dispensers and providers participating in the electronic prescription program under Medicare Part D. The College also urges HHS to accelerate the enumeration of all providers and dispensers to support transition to the NPI for e-prescribing by the onset of the Part D program on January 1, 2006.

The proposed rule does not address the issue of a unique patient identifier. ACP believes that there are patient safety benefits in the use of a unique patient identifier in terms of ensuring accurate matching of prescription and patient data that far outweighs any reasonable privacy or government intrusion concerns. The College recommends that HHS use its resources to place this issue "on the table" for further discussion.

9. The issue of how the e-prescribing system will address "dispense as written" and "brand name medically necessary" instructions.

ACP requests that HHS define their plans for addressing "dispense as written" and "brand name medically necessary" prescription instructions within the federal e-prescribing program.

10. The enactment, monitoring and enforcement of regulations under the Medicare Part D e-prescribing system that ensure that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs.

Both language in the MMA (1860D-4(e)(3)(D)) and the legislation's conference report reflect Congress' intent of ensuring that prescribing health care professionals have ready access to neutral and unbiased information on the full range of covered drugs under the Medicare Part D e-prescribing system. ACP is concerned that the proposed rule does not address this issue.

The College recommends that HHS enact regulations, and the means to monitor and enforce them, that prohibit the transmission of commercial messages within the Medicare Part D e-prescribing system that will unduly bias physician's drug selection. In addition, the College recommends that HHS provide similar protection to ensure that health care prescribers have neutral and unbiased access to information on <u>all</u> covered drugs available in a plan's formulary.

11. The need for incentives to promote provider adoption of electronic prescribing.

ACP believes that e-prescribing, along with electronic health records, has the potential to significantly improve patient safety and quality of care. Unfortunately, recent testimony presented before the NCVHS estimates that only between 5-18 percent of prescribers are

currently conducting e-prescribing. A primary barrier to physician adoption is the cost of buying and implementing these systems, making related changes in the flow of office practices and training staff. ACP recommends the following incentives --- particularly in the smaller physician practices that treat a large number of our Medicare beneficiaries --- to support the significant 10 percent annual expansion of e-prescribing over the next 5 years projected in the proposed rule:

- The availability of financial incentives (e.g. grants, loans, tax incentives) and payment increases contingent on the use of this technology to promote the initial implementation and maintained use of e-prescribing technology. These financial incentives are particularly important in small, rural and underserved clinical settings.
- The expedited revision of the Stark laws and the development of Medicare Anti-kickback law safe harbors (with strong state preemptions) to allow health plans and others, who stand to most benefit financially from adoption, to provide necessary hardware/software, technical assistance and financial incentives to providers.

In addition, there is need for increased discussion and the collection of data on how implementation of e-prescribing may affect physician personal liability risk and related insurance coverage. HHS's has suggested that implementation may decrease medical liability premiums due to its effect of decreasing medication errors. On the other hand, some clinicians have expressed concern about the potential of increased liability risk due to the making of medication judgments based on information (which may or may not be accurate) provided through the e-prescribing system. Furthermore, situations in which physicians choose, based on clinical judgment, to over-ride adverse reaction alerts or other clinical support information ultimately provided by the e-prescribing system also have the potential to increase liability risk This issue clearly requires further exploration and the collection of relevant data.

12. The following issues were not discussed in the proposed rule and need to be addressed in future pilot studies related to the federal e-prescribing system:

- The need for all new standards added to the foundation standards (and other standards ultimately included into the system) to have adequate documentation of successful interaction to ensure the usefulness and correctness of the standard package.
- The need for means of communicating patient choice of pharmacy and change of pharmacy instructions. Optimally, the e-prescribing software should provide more than one pharmacy choice for the patient. In addition, patients who choose to change pharmacies should easily be able to have their prescriptions transferred from one pharmacy to another.
- The need for a "no fill" message to be sent to the prescribing provider.
- The need for performance and notification/acknowledgement of transmissions standards among all parties in the e-prescribing relationship.

- The assessment of the error rate in electronically transmitted prescriptions with the goal of achieving an error rate at least as low as that currently found in the banking industry --- which approaches zero.
- The evaluation of the e-prescribing process to target specific obstacles to adoption in multiple clinic; urban and rural; and small and large practice settings. These evaluations should address financial, staffing and practice flow components of the process.

The ACP appreciates this opportunity to comment on the proposed e-prescribing standards. Please do not hesitate to contact Neil Kirschner on the ACP staff at 202 261-4535 and nkirschner@acponline.org if you have any questions regarding the submitted comments.

Sincerely,

Joseph W. Stubbs MD

Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee

Read by TFM

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**Bonnie Washington**
Vice President Health Policy

**Novartis Pharmaceuticals Corporation**
Washington, DC
701 Pennsylvania Avenue, NW
Washington, DC 20004
USA
Tel 202-662-4378
Fax 202-628-4764
E-Mail bonnie.washington
@pharma.novartis.com
www.novartis.com

April 5, 2005

*BY HAND DELIVERY*

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**RE: Comments on Notice Proposed Rulemaking: Medicare Program; Electronic Prescribing and the Prescription Drug Program [CMS-0011-P]**

Dear Dr. McClellan:

On behalf of Novartis Pharmaceuticals Corporation (Novartis), I am pleased to provide you with Novartis' comments on the first proposed rule on standards for an electronic prescription drug program as required by the Medicare Modernization Act of 2003 (MMA). Novartis Pharmaceuticals is part of the Novartis Group of Companies, a world leader in healthcare with core businesses in pharmaceuticals, consumer health, generics, eye-care, and animal health.

We understand that this proposed rule is the first of several documents that CMS will be putting forth in its establishment of an electronic prescription program for the Medicare drug benefit, and the comments that follow focus on CMS' general approach and focus as it moves forward with e-prescribing. We commend CMS for it efforts on electronic prescribing thus far, including CMS' recognition that safety and quality are of utmost importance. We also recognize CMS' efforts to initially move forward in finalizing only those standards that have broad support and adequate industry experience and we hope that CMS continues to move in such a prudent manner in the future.

If you have any questions or require clarification on any of our comments, please do not hesitate to contact me.

Sincerely,

Bonnie Washington

Bonnie Washington
Vice President, Health Policy
Novartis Pharmaceuticals Corporation
202-662-4378

NOVARTIS

**NOVARTIS PHARMACEUTICALS CORPORATION**
**COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)**

***COMMENTS TO "BACKGROUND" – CMS-0011-P***

**Recommendation: CMS should ensure that patient safety and quality remain the first priority in implementing e-prescribing and that the physician's role is protected.**

**Comments:** Novartis commends CMS for its commitment to improving patient safety, promoting quality of care, and reducing medical errors. We also recognize the potential value e-prescribing holds for all stakeholders in the health care system. Although utilization of e-prescribing technology is growing, it is clear that its use is far from widespread and that there are many unknowns regarding its impact on providers and patients, particularly older Americans.

We urge CMS, in coordination with the Agency for Healthcare Research and Quality (AHRQ), to evaluate the impact and utilization of e-prescribing during both pilot testing and once the e-prescription standards are finalized, and to widely disseminate information on its impact on patients and overall value.

We recognize that e-prescribing will be an important tool to improve safety and quality in the Medicare program and believe strongly that e-prescribing should also support the clinical judgment of physicians. Therefore, any incentives utilized in such a program should support the physician's role in the care process and appropriately reward physicians for improvements to safety and quality. Incentive payments based solely on physician cost containment disregard the primary goals and value of e-prescribing and the legislators' intent.

**Recommendation: An e-prescribing system should provide key information at the point of care.**

**Comments:** An e-prescribing system should provide physicians with the information needed to discuss drug therapy with the patient at the point of care. E-prescribing should facilitate these types of processes, including allowing physicians to efficiently determine the most appropriate drugs and course of treatment available for particular beneficiaries through mechanisms such as electronic prior authorization. Simplicity will be a significant factor in determining whether prescribers embrace e-prescribing, and the value of an e-prescription system will be compromised if prescribers do not have immediate access to the necessary information and are forced to use alternative systems that are slower, more complicated, or simply unavailable at the point of care. Additionally, an e-prescribing system should alert prescribers to provide beneficiaries with immediate notification of their right to request an exception or appeal and the information required to do so.

**NOVARTIS PHARMACEUTICALS CORPORATION**
**COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)**

**Recommendation : CMS standards for the e-prescribing user interface should promote physician treatment options.**

**Comments:** The standards CMS adopts for formulary and benefit coverage information should provide beneficiaries with easy access to the comprehensive list of available drugs.

CMS and the National Committee on Vital and Health Statistics (NCVHS) should continue to work together with key stakeholders to develop relevant and appropriate standards to ensure that under the e-prescribing program, physicians have easy access to the comprehensive list of available drugs. Such information should be presented in a single, neutral, and comprehensive manner (for example, listed alphabetically). Additionally, the user interface must not create any barriers for physicians to prescribe medications that, for example, are on the formulary but are in a higher cost-sharing tier if the physician decides that the drug on the higher tier is medically necessary. Appropriate display of such information is necessary to ensure that the prescriber easily understands the full range of prescribing options available for the patient, and is not inappropriately influenced, and that the display does not impede decision making or place a burden on those using the system.

**Recommendation: E-prescribing standards should reflect the MMA's prohibition on commercial messaging and CMS should work to provide more detailed guidance on this issue.**

**Comments:** The law specifically prohibits the use of inappropriate messaging such as marketing or commercial messages. We strongly urge CMS to work with NCVHS to investigate this issue in more detail, including gathering input from all stakeholders, with the goal of providing clear guidance to plans on the types of messages that are/are not appropriate.

Different types of standards related to messaging may be required. For example, messages that appear before the prescriber begins the decision making process may be less likely to convey specific or appropriate information used in the prescribing process and more likely to contain advertising. Messages sent to the prescriber after a prescription has been transmitted may be problematic if they are intended to pressure the prescriber to change an earlier prescribing decision rather than to correct a prescribing error. Given this, we urge CMS consider any such messages to be plan marketing material and to review these messages as such during any CMS review of a plan's marketing materials.

Messages related to therapeutic alternatives also raise a range of issues. For example, what claims will be made about purported alternatives, and what qualifications or disclaimers will be included? Because such communications will consist largely of subjective judgements, the integrity of such information is of concern. Developing and testing standards in this area will require a significant amount of time because of such complexities, and adoption of standards in this area should be delayed until there is adequate industry consultation and pilot testing in this area.

Until CMS specifies more detailed guidelines, we urge CMS to send a strong signal to plans that it takes this issue very seriously, particularly given the MMA's intent. CMS should state that it will be watching developments in the commercial sector and working with NCVHS to produce appropriate guidance to ensure that e-prescribing does not provide an avenue for inappropriate interference in treatment decisions.

**Recommendation: CMS should reject any incentives that raise Stark and Anti-kickback compliance issues.**

**Comments:** We understand that CMS will propose a new Stark exception in separate rulemaking in the near future and that the Office of the Inspector General (OIG) will propose a new safe harbor under the anti-kickback statute, to cover certain nonmonetary remuneration relating to e-prescribing. Under the MMA, such remuneration could include "hardware, software, or information technology and training services...." We look forward to future guidance from both CMS and the OIG on these issues and the additional opportunities that will be afforded to comment.

We note in this regard that there is an important distinction to be made between monetary and nonmonetary compensation with regard to e-prescribing. Section 423.159(d) of CMS' final rule on the Part D drug benefit authorizes an MA-PD plan (but *not* a PDP) to provide a separate or differential payment to a participating physician who prescribes covered Part D drugs in accordance with the Part D program's e-prescribing standards. This regulatory provision, based on section 102(b) of the MMA, is intended to promote e-prescribing by MA plans. The MMA provides that the differential payment may take into consideration a physician's costs in implementing an e-prescription program and may be increased for physicians who significantly increase: (i) formulary compliance; (ii) therapeutic substitution; (iii) avoidance of adverse drug interactions; and (iv) efficiencies by reducing administrative costs. The MMA also provides that additional or increased payments for e-prescribing may be structured in the same manner as a PDP sponsor's medication therapy management fees to pharmacists under section 1860D-4(c)(2)(E) of the Act.

It is important to note that the future e-prescribing safe harbors to the Stark and anti-kickback statutes will be limited to the provision of nonmonetary remuneration, as defined above. Among other things, such protection would extend to support provided by a PDP sponsor or MA organization to network pharmacists, pharmacies, and prescribing health care professionals. This legislative provision for fraud and abuse protection of IT support does not, however, extend to an MA-PD plan's direct *monetary* payments to physicians to promote e-prescribing programs. Such payments are also distinguishable from medication therapy management fees because the remuneration goes directly to prescribing physicians rather than to dispensing pharmacies.

**NOVARTIS PHARMACEUTICALS CORPORATION**
**COMMENTS ON CMS PROPOSED RULE (CMS-0011-P)**

We concur with CMS's evident concern (as reflected in its preliminary solicitation of public comment on the issue) that an MA-PD plan's differential/increased payments to a physician who e-prescribes can raise substantial fraud and abuse issues. Given the nature of the proposed payments to prescribing physicians and the broad implementation latitude afforded MA-PDs choosing to pay physicians for e-prescriptions, serious fraud and abuse concerns could arise under both the Stark law and the anti-kickback statute, as described below.

A. Stark Law Compliance Issues

A serious Stark law compliance issue would arise if an MA-PD plan with its own in-house and/or mail order pharmacy were to make a direct payment to a prescribing physician under the e-prescription program. The final Stark II (Phase II) regulations indicate that CMS will expand the definition of "outpatient prescription drugs" (i.e., one of the designated health services ("DHS") to which the Stark law applies) to include covered Part D drugs provided for in the MMA, in addition to drugs covered under Medicare Part B. 69 Fed. Reg. 16,054, 16,104 (2004). An MA-PD plan with its own pharmacy therefore would become a DHS provider with a direct financial relationship (i.e., a compensation arrangement including, among other things, the differential payment for e-prescribing) with a referring physician. That relationship would trigger application of the Stark law. For the reasons outlined below, we do not believe the differential payment arrangements would be protected by any of the Stark law's exceptions. Therefore, referrals to the MA plan's pharmacy by a physician receiving differential or increased payments would violate the Stark law. In turn, submission of drug claims to Medicare resulting from those referrals would also be prohibited.

The Stark law includes a general exception, protecting both ownership and compensation arrangements with referring physicians, for services provided by certain types of prepaid plans to their enrollees. 42 U.S.C. § 1395nn(b)(3). Prepaid plans generally include those with Medicare risk contracts, such as MA plans. The Stark law's implementing regulations, however, provide further guidance on the scope of this exception, and it is the regulations that call into serious question the applicability of the exception to an MA-PD plan's differential payments to a referring physician for e-prescribing drugs for plan enrollees. The regulation describing the scope of protection for prepaid plans provides, in pertinent part, as follows:

> Services furnished by an organization (or its contractors or subcontractors) to enrollees of one of the following prepaid health plans [including HMOs and CMPs contracting with CMS under section 1876 of the Act] **(not including services provided to enrollees in any other plan or line of business offered or administered by the same organization)**....

42 C.F.R § 411.355(c) (emphasis added).

We believe that the bolded parenthetical would operate to make this Stark exception inapplicable. Medicare Part D payments to an MA plan are separate and distinct from the program's capitated payment to the plan for the standard Medicare benefits it provides under its risk contract. Although the Part D payment for the voluntary prescription drug program will include a risk-adjusted, capitated component calculated separately for MD-PD plan enrollees, it also will include cost-based payment components in connection with low-income subsidies, the catastrophic drug benefit, and risk-corridor adjustments. In short, the MA-PD plan design and payment system is clearly distinct from the MA capitated payment plan for standard Medicare benefits. Accordingly, the MA-PD operation constitutes a distinct plan operating, in essence, a separate line of business for the MA entity, taking it outside the scope of protection for prepaid plans defined in the regulation set forth above.

Nor do we believe that an MA-PD plan's differential payment to e-prescribing physicians would qualify for other Stark law exceptions for compensation arrangements. For example, the "fair market value exception" protects certain payment arrangements between an entity and a referring physician "for the provision of items or services by the physician..." when the payments are set in advance at a fair market value ("FMV") rate not taking into account the volume or value of referrals, and when other requirements are satisfied. 42 C.F.R. § 411.357(l). Under the e-prescribing program, the physician will be paid for simply writing a prescription electronically rather than in the traditional paper-based method. It is doubtful that merely writing a prescription would qualify as a separate "service" for which a physician could appropriately be compensated under this exception. The issuance of a prescription is an integral part of a patient's office visit or other medical evaluation or treatment service for which a physician arguably already is compensated under the Medicare physician fee schedule. In the Preamble to the Stark II (Phase II) regulations, CMS firmly resisted commenters' suggestions that it should expand the fair market value exception's scope of protection to remunerative relationships beyond the provision of "items and services." 69 Fed. Reg. at 16,111. Moreover, because this exception requires payment to be at an FMV rate, the differential payment for writing an electronic script would duplicate the Medicare payment already made for the beneficiary's physician visit. It would be impossible to assign a separate FMV rate for merely writing the prescription. Accordingly, the MA-PD plan's differential and increased payment to referring physicians for e-prescribing would fail to qualify for the Stark law's fair market value or similar compensation arrangement exceptions.[1] We must therefore conclude that this Stark law compliance failure would prevent the lawful implementation of this aspect of the e-prescribing program described in the proposed regulations.

[1] Similar problems would exist with the Stark regulations' exceptions for personal service arrangements (42 C.F.R. § 411.357(d)) and bona fide employment relationships (42 C.F.R. § 411.357(c)).

B. Anti-Kickback Statute Compliance Issues

Although the proposed rule's differential payment provisions seek to induce physicians to use electronic prescriptions rather than handwritten ones, Novartis believes the broad discretion afforded MA-PD plans in structuring these payments could well produce the unintended consequence of generating payments to prescribing physicians that violate the anti-kickback statute. Further, no safe harbor protection would be available to protect these payments under either existing regulations or those to be developed under the MMA for nonmonetary remuneration in connection with IT support and the like. We summarize below our concerns about potential non-compliance with the anti-kickback statute.

The anti-kickback statute has been interpreted to prohibit any arrangement where one purpose of the remuneration is for the referral of Medicare- or Medicaid-covered services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Given an MA-PD plan's broad discretion under the proposed regulations to structure differential payments to e-prescribing physicians, there is nothing to prevent a plan from paying a higher differential payment when a Medicare beneficiary has a Part D prescription filled at the MA-PD plan's own in-house or mail order pharmacy. In our view, such a payment structure would clearly constitute an inducement to the physician to use the plan's own pharmacy for a Medicare-covered prescription drug in violation of the anti-kickback statute.

Finally, the OIG issued a Special Fraud Alert in 1994 addressing anti-kickback issues related to prescription drug marketing practices. The OIG raised serious anti-kickback statute concerns in connection with payments to prescribing physicians that can interfere with a physician's judgment in determining the most appropriate treatment for a patient. We respectfully submit that the proposed differential payments to e-prescribing physicians raise the same serious concern and ought to be reconsidered.

Read on TOM APR 4 2005 #11 84

# ahca
# American Health Care Association

1201 L Street, NW, Washington, DC 20005-4014
Main Telephone: 202-842-4444
Main Fax: 202-842-3860 2nd Main Fax: 202-289-4253
Writer's Telephone: 202-898-2828
Writer's E-Mail: hdaub@ahca.org
www.ahca.org



April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 309-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201
Attn: CMS-0011-P

***Re: Comments On Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P***

Dear Dr. McClellan:

The American Health Care Association (AHCA) appreciates the opportunity to comment on the proposed rule *Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule 70 Federal Register 6256, February 4, 200569 Federal Register 46632, CMS-0011-P.* AHCA is the nation's leading long term care (LTC) organization. AHCA and its membership are committed to performance excellence and Quality First, a covenant for healthy, affordable and ethical LTC. AHCA represents more than 10,000 non-profit and proprietary facilities dedicated to continuous improvement in the delivery of professional and compassionate care provided daily by millions of caring employees to more than 1.5 million of our nation's frail, elderly and disabled citizens who live in nursing facilities, assisted living residences, subacute centers and homes for persons with mental retardation and developmental disabilities.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L.108-173, signed into law on December 8, 2004, took a giant step forward in providing increased benefits to Medicare beneficiaries in the critical area of prescription drugs. The legislation established a new voluntary prescription drug benefit under a new Part D of the Medicare program which is to be effective January 1, 2006. The new Medicare Part D will provide many benefits and also many challenges.

AHCA was pleased to submit comments on the proposed Part D rule implementing the MMA,[1] particularly in areas directly affecting LTC residents and LTC facilities.[2] We were gratified at CMS' responsiveness to our concerns in the Part D final rule[3] and in the guidance that CMS issued on March 12 regarding performance and service criteria for network LTC pharmacies (NLTCPS) and requirements for Part D Plan sponsors for a process for coverage transitions. There is still work to be done and many issues to be addressed, but we believe that CMS has made great progress. We value being part of the mutual effort of the government and the private sector to help Part D achieve its full potential of achieving better lives for our citizens, and in particular the lives of residents in LTC, and in continuing to improve the quality of their care.

The MMA also required that prescriptions and certain other information for covered drugs that are transmitted electronically must comply with final uniform standards promulgated no later than 2008 by the Secretary. These standards must meet MMA's requirements, as well as be compatible with other standards, including standards adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). In the final Part D rule published on January 28, 2005, CMS requires Medicare Part D Prescription Drug Plan (PDP) sponsors, Medicare Advantage (MA) organizations offering Medicare Advantage-Prescription Drug (MA-PD) plans, and other Part D sponsors to support and comply with electronic prescribing standards once final standards are in effect, including any standards that are in effect before the drug benefit begins in 2006. On February 4, 2005, CMS published the proposed rule providing the first set of uniform final standards for electronic prescribing (e-prescribing) under Part D for which we are now providing comments.

***The Importance of E-Prescribing in the LTC Environment***

The use of the standards is mandatory solely for Part D sponsors and even then only to receive or reply to e-prescribing transactions initiated by other entities. Providers that prescribe or dispense Part D drugs are required to comply with the standards only when they electronically transmit prescription information or certain other related information.

CMS indicates that while 75 percent of the 57, 208 pharmacies in the United States already have e-prescribing capability, only between 5 and 18 percent of physicians and other clinicians are e-prescribing. Except for certain exceptional initiatives,

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[1] *Medicare Program; Medicare Prescription Drug Benefit, Proposed Rule*, 69 Federal Register *46632*, August 3, 2004.

[2] We use the term LTC facilities to refer to nursing facilities and intermediate care facilities for the mentally retarded (ICFs/MR). CMS expanded the definition of the term "long term care" facilities in 42 CFR 423.100 of the Part D final rule to encompass ICFs/MR.

[3] *Medicare Program; Medicare Prescription Drug Benefit, Final Rule*, 70 Federal Register 4193, January 28, 2005.

AHCA assumes that few if any physicians are e-prescribing with respect to residents of LTC facilities. This picture must change. The benefits of e-prescribing for patients are enormous. CMS articulates just some of the potential benefits as follows:

- E-prescribing can help prevent medication errors because, at the time of prescribing, each prescription can be checked electronically for dosage, interactions with other medications, and therapeutic duplication.
- E-prescribing can also improve quality, efficiency, and reduce costs, by:
  - Improving patient safety and quality of care through immediate access to medication history information, and the prevention of adverse drug events;
  - Providing information about formulary-based drug coverage, including formulary alternatives and co-pay information;
  - Speeding up the process of renewing medications; and
  - Providing instant connectivity between the health care provider, the LTC pharmacy, health plans/PBMs, and other entities, improving the speed and accuracy of prescription dispensing, pharmacy callbacks, renewal requests, eligibility checks, and medication history.
- E-prescribing also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.

In addition to the anticipated reductions in adverse health events associated with anticipated improvements in prescription drug compliance, CMS also believes that many elements of the Medicare prescription drug benefit, including quality assurance, better information on drug costs (for example, through generic substitution), and medication therapy management (which is designed to improve medication use and reduce the risk of adverse events, including adverse drug interactions) will be enhanced by e-prescribing.

CMS believes that these improvements, enabled by e-prescribing programs, will occur through, among other things, improved prescription drug-related quality and disease management efforts, and ongoing improvements in information systems used to detect various kinds of prescribing errors, including duplicate prescriptions, drug-drug interactions, incorrect dosage calculations, and problems relating to coordination between pharmacies and health providers. CMS also believes that additional reductions in errors and additional improvements in prescription choices based on the latest available evidence will occur over time as the electronic prescription program provisions of the MMA are implemented.

It is clear that all these benefits and enhancements to quality of pharmacy care, deriving in great part from advancements such as e-prescribing, must be provided to LTC residents as well as Part D beneficiaries who do not reside in LTC facilities. They will constitute an advancement in -- and become a fundamental and integral

part of -- the quality of care in LTC facilities. Nationally, there are 1.6 million nursing home residents; this is a major group taking multiple medications and each medication requiring multiple nurse/physician communications (phone and fax) on a regular basis.

The benefits of e-prescribing that CMS articulates could assist LTC facility compliance with Medicare and Medicaid requirements of participation. For example, the survey guidance for requirements governing medication errors and unnecessary drugs is currently undergoing major revision under CMS contract to the American Institutes for Research (AIR). The AIR product is intended to provide specific information to assist surveyors in making appropriate determinations and severity assessment of noncompliance cited under the related regulations. It is inconsistent for CMS on the one hand to "beef up" the survey guidance in this area, while on the other hand ignoring e-prescribing as a tool that could assist nursing facilities to achieve and sustain compliance.

Yet, CMS' proposed rule is completely silent on the impact of the e-prescribing standards in the LTC setting and thus utterly devoid of any recognition of the importance of e-prescribing to the LTC environment. In fact, the proposed foundation standards would not accommodate the LTC pharmacy services model because the standards are based on direct communication between the prescriber and the retail pharmacy and do not recognize the third critical entity involved in providing drugs in the LTC setting -- the LTC provider. Likewise, CMS has also failed to provide any consideration of how e-prescribing standards might require modification and further development to meet the complex operational and regulatory environment of LTC facility pharmacy services and the role of the consultant pharmacist, or addressed how the development and adoption of LTC e-prescribing could be supported and incentivized. Thus, CMS has not raised the issue of protection for LTC providers under the Anti-kickback statue related to certain e-prescribing incentives -- protection which the Office of Inspector General (OIG) intends to afford other providers, such as physicians, in further regulation.

It is also clear that if CMS hopes to substantively increase the participation of physicians in e-prescribing for Medicare patients, it cannot ignore the LTC patient population. Failure to address the LTC environment in the development of e-prescribing can have serious adverse consequences: it could disincentivize and impede physicians who have LTC patients from adopting e-prescribing technology and or it could disincentivize physicians from caring for LTC patients, thus exacerbating a bias that exists today. Without concurrently including LTC in physician e-prescribing efforts, chemotherapeutic care for the chronically ill will continue to be delivered in a silo, devoid of all benefits from instant information exchange, leaving the physician to deal with e-prescribing for one set of patients and continued use of phone and fax for others. Having physicians using multiple medication systems is confusing, burdensome, costly and will lead to error. This

situation, alone, has the propensity to derail physician e-prescribing technology efforts.

In the final e-prescribing rule and in its future activities in this area, CMS must rectify the omission of consideration of LTC and LTC residents. To that end, we recommend below several steps that CMS should take.

***Development of Standards for the LTC Facility Environment***

First, we ask that CMS work with the National Council for Prescription Drug Programs (NCPDP) on standards that will make possible and promote e-prescribing in the LTC environment. CMS has adopted the prescription SCRIPT standard of the NCPDP and certain NCPDP standards for eligibility. These final standards are referred to as foundation standards by CMS because they would be the first final set of final standards adopted for an electronic prescribing program. According to CMS adequate industry experience exists with respect to these proposed standards thus allowing CMS to propose and adopt these foundation standards as final standards without pilot testing. However, these standards, based on direct communication between the prescriber and the retail pharmacy, do not accommodate the LTC pharmacy services model. NCPDP has developed a work group to address e-prescribing in the LTC environment. We ask that CMS work with the group developed by the NCPDP to provide design alternatives for standards used within the LTC setting. We understand that the design alternatives being examined by the work group are focused on accounting for and connecting all three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility.

In order to ensure that futher e-prescribing standards work within the context of the three-way prescriber, LTC provider, LTC pharmacy environment, AHCA recommends that additional standards, as well as updates and revisions to e-prescribing standards be subject to formal agency rulemaking. E-prescribing standards represent substantive responsibilities for LTC providers, prescribers, and LTC pharmacies, and a Notice of Proposed Rulemaking (NPRM) process is the only way LTC providers can be assured of notice and an opportunity to comment on e-prescribing standards that affect the services provided to nursing home residents.

As CMS knows, the LTC facility bears the primary responsibility for safe and effective drug distribution to its residents. For example, the requirements with respect to nursing facilities are manifold and strict, as they should be. The core mandate is that "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychological well-being in accordance with the comprehensive assessment and plan of care." 42 CFR 483.25. Further, "A drug whether prescribed on a routine, emergency, or as needed basis, must be provided in a timely manner. If failure to provide a prescribed drug in a timely manner causes the resident discomfort

or endangers his or her health and safety, then this requirement is not met." 42 CFR 383.60 and 483.75(h). In addition, as a vital part of the quality of care requirements, the facility must ensure that it is free of medication error rates of 5 percent or greater; and residents are free of any significant medication errors. 42 CFR 483.25 (m).

As indicated above, these regulatory mandates place the ultimate responsibility for safe and effective drug distribution with the LTC facility. A critical aspect of this responsibility is the fact that the medical record of the patient is kept at the LTC facility. Thus, a key operative concept in designing an operative LTC e-prescribing system is to acknowledge the responsibilities of the LTC facility, the role of the LTC facility as the guardian of the resident's medical record, and the key role of LTC facility staff.

The act of prescribing in the LTC facility environment involves direct communication between LTC nursing staff and the physician and further communication between the LTC facility staff and the LTC pharmacy. No matter how streamlined the process may become, the LTC facility stands at the heart of the process. Again, this is a model that involves three entities: the physician, the pharmacy, and the LTC facility. Any e-prescribing system that provides the benefits of e-prescribing to LTC residents must involve all three entities.

Most importantly, the system must facilitate and support the ability of the LTC facility to provide the highest quality of care for its residents and meet all of the mandates of law and regulation pertaining to the provision of pharmacy services. Thus, to reiterate, we ask that CMS work with the NCPDP designated workgroup to provide design alternatives for standards used within the LTC profession which will address the vital roles of the three critical entities in the provision of LTC pharmacy services: the physician, the pharmacy and the LTC facility. As CMS moves toward full implementation of electronic prescribing for medications covered under Medicare Part D, it is essential that the proper framework be developed for prescribing medications for LTC residents.

***Pilot Testing and Demonstrations***

Secondly, the MMA requires pilot testing for initial standards for which adequate industry experience is lacking. Testing of such standards would, pursuant to the proposed rule, occur during the 2006 calendar year. The results of the pilot project would be evaluated and, based upon those results, final standards will be published not later than April 1, 2008. The proposed rule indicates that in order to conduct the pilot project, the Secretary will enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals will electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with these standards. The Secretary is mandated to conduct an evaluation of the pilot project,

and to submit a report to the Congress on the evaluation, not later than April 1, 2007. Again, there is no inclusion of LTC providers.

We reiterate our request that CMS work with the NCPDP to develop and pilot test standards that are appropriate for the LTC environment. We are concerned that any pilot study will not provide a true picture of standardization needs for electronic prescribing unless the pilots include the full spectrum of health care, including long-term care. AHCA also recommends that the evaluation of the pilot testing specifically address the experience of physicians, LTC providers, and LTC pharmacies in its report to Congress on the outcome of the pilot testing.

Lastly, we ask that CMS use its demonstration authority to develop and test various appropriate e-prescribing models in LTC facility environments.

***Overcoming Barriers to E-Prescribing***

Third, CMS must help LTC overcome barriers to the development and application of LTC e-prescribing. In the proposed rule, CMS clearly recognizes the barriers to increased usage of e-prescribing by physicians. One major barrier is the cost of buying and installing a system which includes the time involved in training staff and changing record systems from paper to electronic. CMS also cites lack of reimbursement for e-prescribing costs and resources. Since CMS does not address the LTC environment, the agency never discusses the fact that such costs also will be borne by both LTC facilities and LTC pharmacies in evolving toward e-prescribing.

CMS should first assist the LTC profession in trying to estimate and quantify these costs and then work with LTC providers and pharmacies to find ways to assist the funding of this new technology. For example, with regard to physicians, CMS acknowledges that some health plans have offered hardware and software for e-prescribing and reimbursement for the first year's e-prescribing subscription fees. CMS states that the OIG will create an exception to the Stark law and an Antikickback safe harbor for such e-prescribing physician incentives. If health plans consider similarly incentivizing LTC pharmacies and facilities to join physicians in the three-way LTC e-prescribing environment, then CMS and the OIG should consider similar legal protection for LTC facilities and pharmacies.

Lastly, as we have indicated above, a concomitant barrier to overall adoption of e-prescribing is prolonging an environment in which physicians would face having to use multiple prescribing systems: with e-prescribing for one set of patients and continued use of phone and fax for others. Thus assisting the LTC profession to meet the costs of participating in e-prescribing will help to hasten the adoption of this critical system by all physicians.

***CMS Support for LTC Profession Efforts in Information Technology, Adoption of Electronic Records and E-prescribing***

Last but not least, e-prescribing is only one facet of the overall revolution that is occurring in the development and adoption of health information technology and the development of electronic health records (EHRs). AHCA is at the forefront of an intensive comprehensive effort to support the development of electronic records and their adoption by LTC providers and the development of appropriate and necessary health information technology (HIT) for introduction to, and adoption by, LTC providers. We are on record with many efforts in these areas.

CMS itself acknowledges that an e-prescribing program (including drug-to-drug interaction checking, dosage adjustments and information on the availability of lower cost therapeutic alternatives for which standards will be adopted in the future) is one part of a comprehensive EHR system with decision support functionality and that it must be interoperable with other functions of an EHR. CMS indicates that the need for interoperability between these systems will become even more critical in the future when patient medical history standards are adopted. CMS acknowledges that one option might have been to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time.

However, CMS rejected this approach since it would postpone the implementation of any e-prescribing functionality, including the attendant benefits and was beyond the scope of the MMA. Instead CMS is attempting to propose foundation standards that are appropriately accredited and have adequate industry experience. CMS believes that this will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. CMS solicits comment on this approach, as well as on other critical success factors for assuring interoperability.

We agree with this approach since it is our belief that movement forward must be made on all these fronts -- but not without LTC -- and not without the support of CMS as AHCA proceeds with its many initiatives. For instance, we are identifying, reviewing, synthesizing and distributing existing steps/protocol for selecting software, systems and vendors; identifying the need for additional or enhanced criteria to improve the selection protocols; organizing an LTC summit bringing together LTC operators, vendors, and government officials; identifying products available and trying to resolve impediments to product development; collaborating on the Continuity of Care Record (CCR) as part of our EHR initiative; reviewing and commenting on HL7 EHR standards; and promoting LTC profession's efforts to align with Regional Health Information Organizations (RHIOs). This includes monitoring barriers preventing LTC from participating and helping AHCA affiliated state associations efforts to promote LTC partnerships with RHIOs.

***Conclusion***

In conclusion, LTC residents deserve the finest quality care possible. LTC providers have made enormous strides in improving and enhancing that care. They cannot be left behind as technological innovation is increasingly introduced into the health care environment. The LTC profession assisted by AHCA is taking giant steps in promoting the development of and access to quality enhancing technology.

In the final rule, CMS should address e-prescribing standards that would apply to the provision of pharmacy services in the LTC profession. Further it should articulate the ways and means that it would employ to promote and support e-prescribing in the LTC facility environment. This may include pilot testing, demonstrations and encouragement of health plan support for incentivizing LTC facilities and pharmacies to participate in e-prescribing. I would gladly work with you on these issues and welcome discussion with you on inclusion of the LTC in CMS' e-prescribing efforts.

Sincerely,

Hal Daub
President and CEO

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Legal
Pfizer Inc
235 East 42nd Street 25/3
New York, NY 10017
Tel 212 733 8271 Fax 212 573 1445
Cell 302 545 0250
Email w.charles.lucas@pfizer.com

**W. Charles Lucas**
Senior Assistant General Counsel
Legal External Affairs Group

April 5, 2005

**By Hand**

Honorable Mark B. McClellan
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS–0011-P
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-0011-P; Medicare Program; E-Prescribing and the Prescription Drug Program**

Dear Administrator McClellan:

I am writing on behalf of Pfizer Inc. a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. We appreciate the opportunity to comment on the Medicare E-Prescribing Proposed Rule,[1] and look forward to working with the Centers for Medicare & Medicaid Services (CMS) to ensure that its provisions are implemented in a manner that best meets the needs of patients.

## I. BACKGROUND

Pfizer strongly supports the principles of electronic prescribing outlined in the Medicare Modernization Act of 2003 (MMA) and discussed in greater detail in the Proposed Rule. We believe that electronic prescribing offers significant potential to improve the quality of healthcare by reducing medication errors, improving process and cost efficiencies, and increasing patient therapeutic compliance. Looking forward, we also believe that electronic prescribing may serve

[1] See 70 Fed. Reg. 6,256 (Feb. 4, 2005).

as a beachhead for the adoption of electronic medical records and the electronic interchange of health information between interoperable healthcare systems.

Consequently, Pfizer has been very involved in the debate surrounding e-prescribing and the standards that will govern the process. In 2004, we testified before the National Committee on Vital and Health Statistics (NCVHS) regarding a number of specific policy and process concerns that were addressed in the MMA regarding inappropriate messaging and the potential for abuse of e-prescribing technologies. We presented the committee with examples of various behaviors, based on our experience with e-prescribing vendors and technologies, demonstrating the risks of failing to address these issues. Pfizer also submitted comments to CMS as part of the rulemaking process surrounding the new Medicare Part D outpatient prescription drug benefit that, while supporting the e-prescribing program in general, again highlighted our policy and process concerns. Therefore, we were quite concerned that the Proposed Rule made little mention of these issues, focusing instead on the technical standards necessary to transmit information among prescribers, dispensers, and payers. As described below, while Pfizer is strongly supportive of e-prescribing, we remain concerned that the autonomy of the patient-physician relationship may be adversely affected if standards are not designed and evaluated so as to avoid the inappropriate use of e-prescribing and its accompanying technologies.

## II. THE PROPOSED RULE

### A. We Strongly Support the Use of Pilot Testing to Assess and Evaluate Potential E-Prescribing Standards

Pfizer believes that pilot testing of all e-prescribing standards is necessary to ensure that such standards honor the intent of Congress that physician – and consequently patient – autonomy not be adversely affected by the use of new technologies. E-prescribing, as envisioned by the MMA, will operate on an unprecedented scale. Recognizing this, Congress provided in the MMA for a specific, detailed methodology for developing, recommending, and testing e-prescribing standards. Specifically, the MMA directed CMS to engage NCVHS to assist in developing recommendations for uniform e-prescribing standards, and then to "develop, adopt, recognize, or modify initial uniform standards" based on these recommendations.[2] Next, as noted in the Proposed Rule,[3] CMS is to conduct a voluntary pilot project in 2006 to test its initial standards, to evaluate the results of the test, and to report the results to Congress by April 1,

[2] 42 U.S.C. § 1395w-104(e)(4).

[3] 70 Fed. Reg. at 6,228.

2007.[4] Final standards are due by April 1, 2008.[5] We believe that this process should not be circumvented by implementing standards prematurely without pilot testing.

To assist in this process, Pfizer has played an active role in the discussions surrounding the scope and goals of the 2006 pilot testing program. We recently provided the agency with a number of recommendations for its consideration in developing the pilot projects, including a recommendation that CMS pilot test all e-prescribing standards, including the foundation standards discussed below.[6] Many physicians will not voluntarily adopt e-prescribing unless sufficient evidence exists demonstrating its safety for patients and its affordability for their practices. Pilot testing therefore is absolutely critical to ensure that any proposed standards, including the proposed foundation standards, will function on a practical level as Congress intended and are widely adopted by physicians.

### B. We Support CMS's Proposed Industry Experience Criteria and Foundation Standards

While not supplanting the need for pilot testing, Pfizer also supports CMS's proposed criteria for evaluating industry experience with potential e-prescribing standards. In particular, we support the use of ANSI accreditation as an important element in evaluating the industry experience that will be necessary before an e-prescribing standard is promulgated. As noted in the Proposed Rule, the ANSI accreditation process is accessible to all interested stakeholders.[7] This process provides a framework for ensuring that all stakeholders are able to participate in shaping the standards, which in turn increases the potential that any final standard will address and be responsive to industry needs.

We also agree that any e-prescribing standard should be widely implemented by those entities that will be subject to the electronic prescribing requirements and should be recognized by key stakeholders as an industry standard.[8] Industry implementation is crucial to ensuring that any proposed standard will be capable of operating in real-world settings. Similarly, broad industry recognition is important to ensure that the standard is commercially viable, and not

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[4] See 42 U.S.C. § 1395w-104(e)(4)(C). CMS may only forgo the pilot project if it finds there is sufficient industry experience with respect to the initial standards. See id. § 1395w-104(e)(3)(C).

[5] See id. § 1395w-104(e)(4)(D).

[6] See Tab A.

[7] See 70 Fed. Reg. at 6,261.

[8] See id.

simply one of many "standards" currently in use that may not survive if the industry subsequently coalesces around a single standard.

Significantly, while we believe the technical standards proposed as foundation standards, the NCPDP SCRIPT and Telecommunication standards and the X12N 270/271 standards, satisfy these proposed requirements, pilot testing is appropriate because of the lack of industry experience operating these three standards together and within the context of an entirely new Medicare prescription drug benefit program. We are concerned that joint usage of these standards may generate complications or other issues not present when the standards are used individually that, in turn, could discourage physicians from participating in the program. Therefore, the proposed foundation standards should also be subject to pilot testing in 2006.

### C. Future Standards Should Provide Appropriate Safeguards to Protect Patients

#### 1. CMS Should Conduct Further Rulemaking and Pilot Testing Prior to Adopting Formulary and Medication History Standards

In the Proposed Rule, CMS indicates that it may adopt formulary and medication history standards as foundation standards if certain criteria, referred to as "critical characteristics," are satisfied.[9] CMS also specifically states that the RxHub protocols may serve as the basis for such standards and solicits comment on this and other candidate standards.[10] Pfizer has a number of concerns about this proposed action.

First, the Proposed Rule does not provide sufficient information to allow stakeholders to submit informed comments on this issue.[11] Other than discussing the possible use of the RxHub protocols as the potential basis for formulary and medication history standards, the Proposed Rule merely identifies the critical characteristics that CMS proposes to use to evaluate such standards.[12] This proposal does not provide any specific guidance as to what final standards CMS may ultimately adopt. Thus, to adopt final standards based solely on this discussion would deprive the public of the ability to submit meaningful comments. We urge CMS instead to review the comments it will receive on the proposed critical characteristics and then propose specific standards for formulary and medication history data for public comment and pilot testing. This will ensure that the greatest number of interested stakeholders can participate in

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[9] See id. at 6,263.

[10] See id.

[11] See id.

[12] See id. at 6,263-64.

this process and provide relevant comments to the agency. If CMS ultimately adopts formulary and medication history standards without explicitly providing specific standards for public consideration and without pilot testing such standards, the careful deliberative process envisioned by Congress would be severely compromised.

We also believe that the RxHub protocols should not be used, either as standards themselves or as the basis for formulary and medication history standards. Currently, the RxHub protocols do not satisfy the proposed criteria regarding industry experience and recognition so as to merit adoption without pilot testing. We understand that these protocols are used in a significant number of formulary transactions; however, these transactions are currently conducted among a limited number of entities in a controlled environment. By comparison, the NCPDP SCRIPT standard is widely used across the entire industry by a variety of stakeholders and stakeholder types. Further, the original RxHub protocols that were submitted to NCPDP for accreditation have undergone substantive changes during task group development and review, and the industry has very limited experience with the current versions. Consequently, we do not believe the RxHub protocols should be adopted as standards, or as the basis for standards, without pilot testing.

Further, the RxHub protocols have not received ANSI accreditation, although we understand that RxHub is seeking such status.[13] Clearly, the pursuit of such accreditation is not a substitute for the completed process. Therefore, the protocols should not be adopted as, or as the basis for, foundation standards.

Finally, we are concerned that CMS's critical characteristics fail to consider the above-referenced policy issues identified by Congress in the MMA and its accompanying Conference Report. We discuss these policy concerns more fully below. We urge CMS to expand its critical characteristics – preferably through regulatory language – to include criteria that evaluate whether potential standards adequately address these concerns and to use pilot testing to assess how successfully a potential standard satisfies these additional criteria.

### 2. Congress Has Clearly Proscribed Inappropriate Messaging

While embracing the promise of electronic prescribing, in enacting the MMA, Congress was keenly aware of the potential threat that this technology poses to patient and physician autonomy and specifically addressed this concern in the legislation. In particular, the MMA requires that electronic prescribing standards "allow for the messaging of information only if it

[13] See id. at 6,261.

relates to the appropriate prescribing of drugs, including quality assurance measures and systems [to reduce medication errors, to avoid adverse drug interactions, and to improve medication use]."[14] Similarly, the accompanying Conference Report states that, under electronic prescribing, physicians should have access to "neutral and unbiased information on the full range of covered outpatient drugs," and that Congress did not intend for e-prescribing "to be used as a marketing platform or other mechanism to unduly influence the clinical decisions of physicians."[15]

Senate Finance Committee Chairman Charles E. Grassley (R-IA) further reiterated this intent in a July 26, 2004 letter[16] to NCVHS. In that letter, Sen. Grassley explicitly pointed to provisions in the MMA that are "aimed at addressing issues that could compromise electronic prescribing programs and the underlying intent of these provisions."[17] In citing the statutory prohibition on unrelated messaging, Sen. Grassley stated that this "provision is intended to preclude the transmission of commercial information and to ensure the presentation of neutral and unbiased information with the ultimate objective of protecting patient choice."[18] He also highlighted the aforementioned Conference Report language indicating that Congress did not intend for e-prescribing to be a marketing tool or otherwise unduly influence physicians' clinical decisions.[19]

Relying on this unambiguous Congressional intent, NCVHS expressly recommended to the Secretary of Health and Human Services that the agency adopt regulations "requir[ing] that e-prescribing messages received through e-prescribing applications be free from commercial bias."[20]

Remarkably, the Proposed Rule addresses these concerns in a single sentence,[21] and does not provide any guidance or criteria by which to judge whether or how a standard is to address these issues. In contravention of the clearly expressed intent of Congress, the Proposed Rule

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[14] 42 U.S.C. § 1395w-104(e)(3)(D).

[15] H.R. Conf. Rep. No. 108-391, at 455-56.

[16] See Tab B.

[17] Letter from Sen. Charles E. Grassley, Chair, Senate Finance Committee, to Simon Cohn, Chair, Subcommittee on Standards and Security, NCVHS 1 (July 26, 2004) (hereinafter "Grassley letter").

[18] Id.

[19] See id. at 2 (citing H.R. Conf. Rep. No. 108-391, at 456 (2003)).

[20] Letter from John Lumpkin, Chairman, NCVHS, to Tommy Thompson, Secretary, Department of Health and Human Services 14 (Sept. 2, 2004).

[21] See 70 Fed. Reg. at 6,262,

fails to establish the appropriate parameters around electronic prescribing that are needed to protect patients from inappropriate messaging. Consequently, we strongly urge CMS to develop and implement additional criteria in the regulations that will be considered in evaluating all future e-prescribing standards, including the eventual formulary standards. While CMS could address these issues by simply expanding the critical characteristics discussed in the Preamble to the Proposed Rule, we believe these characteristics should be formalized in regulatory text so as to provide an opportunity for public comment.

**a. Inappropriate Messaging Should Be Broadly Defined**

In general, we urge CMS to promulgate regulations that will create a zone of autonomy that surrounds the physician-patient relationship and protects that relationship from commercial and other inappropriate messaging. This zone should be protected by carefully crafted policies to ensure that these safeguards are not eroded over time. In this regard, we recommend that CMS adopt a broad definition of inappropriate messaging that would extend well beyond traditional advertising and include any non-clinical messaging from any third party – be it a payer, PBM, pharmacy or manufacturer – that is aimed at influencing a physician's choice of drug therapy at the point of prescription or at the point of a patient's choice of pharmacy. Electronic prescribing standards should be designed to improve "patient safety; the quality of care provided to patients; and efficiencies . . . in the delivery of care."[22] We believe an appropriate definition would protect the patient-physician relationship without impeding the transmittal of necessary clinical and benefit information, including a drug's formulary position, cost-sharing, and other relevant benefit restrictions.

**b. Proscribe Payment Arrangements With E-Prescribing Vendors that Reward Drug Switching**

PBMs and prescription drug plans should not pay electronic prescribing vendors to switch prescriptions from the physician's intended selection to a less-costly choice, without specific consideration of the best care for a particular patient. Indeed, e-prescribing vendors should be completely barred from entering into arrangements under which the vendor receives any financial incentives for influencing physician decision-making. We recognize that, in some instances, the preferred formulary drug may achieve the best balance of clinical and financial value for the patient. In other cases, however, there may be drugs that are on-formulary but not preferred, or are off-formulary, which better serve the patient's needs. In these instances, the physician should not be harassed by communications that attempt to persuade her to select a

[22] 42 U.S.C. § 1395w-104(e)(3)(B).

certain drug because it is financially more appealing to the electronic prescribing vendor, PBM, or other stakeholder. Such communications should be prohibited by regulation.

**c. No Interruptive Messages**

In addition, the regulations should flatly proscribe interruptive or "pop-up" messages that try to reverse a physician's intended selection at the point of prescription.[23] We strongly believe that a physician and her patient should be advised of all clinical and financial issues related to the writing of a prescription prior to making this decision, and that such information should be presented in a passive, non-interruptive, manner. Once a physician has made an informed selection, pop-up messaging should not be used to seek to change the physician's prescribing decision solely on the basis of financial considerations. Electronic prescribing standards that would allow for this conduct would fail to achieve the congressionally prescribed objectives for such standards.

**d. Restrict Pre-emptive Messaging**

Pre-emptive messaging, i.e., communications that inform the physician up front that a particular drug is recommended for a particular condition, is also problematic. Such messaging presumably is premised on a relationship between the vendor and either the manufacturer or PBM. It would be reasonable for a vendor to engage in this kind of communication if this messaging is provided independent of any prescription that is being considered for a specific patient. However, if the messaging is being targeted to the physician because she has indicated she is about to prescribe a drug from a certain category, this clearly would be inappropriate and would constitute unrelated messaging that is proscribed under the MMA. Consequently, such messaging should be prohibited because it intrudes on the prescribing transaction and thereby invades the autonomous physician/patient relationship.

**e. Present Formulary Information in a Neutral Manner**

Reflecting the requirement for e-prescribing under the MMA that the physician have access to "neutral and unbiased information on the full range of covered outpatient drugs,"[24] formulary information, to the fullest extent feasible, should be communicated to prescribers in a single, consolidated neutral list.

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[23] Such a prohibition should not include messaging related to patient education or compliance programs that is presented after the physician prescribes a drug but that does not attempt to influence the prescribing decision.

[24] H.R. Conf. Rep. No. 108-391, at 455 (see also Grassley letter, at 1).

We believe that "neutral and unbiased" presentation means that, when a physician prescribes a drug, she should be presented with all pertinent information at the point of prescription, including all of the drugs that may be used to treat a patient's condition. This list should include all of the plan's preferred drugs, but also drugs that are non-preferred or off-formulary. But physicians should not be shown only the preferred drug and then forced to click again to view non-preferred and off-formulary options. If only the preferred choices are presented, it could unduly influence the physician's selection before she has been fully informed of the complete range of choices and may make it less likely that the physician will consider non-preferred drugs that, while not offering the PBM the highest rebate, could be more beneficial to the patient. While accurate formulary information helps inform the physician's decision, formulary presentation should not be used to exert untoward influence on the prescribing process, nor should PBMs or plans be allowed to provide incentives to e-prescribing vendors to structure the interface in a manner that improperly influences the prescribing decision. Additionally, drug information presented within the electronic prescribing environment should be properly sourced and subject to the same rigorous standards of accountability and balance as required by the FDA for pharmaceutical manufacturers.[25]

### D. CMS Should Support the Development of Standards for Real-time Prior Authorization

While we recognize that the Proposed Rule does not specifically address prior authorization, we encourage the agency to consider the implications of the present rulemaking on the future development of a real-time, electronic prior authorization standard, particularly in relation to the potential development of a formulary standard.

Prior authorization was the subject of significant discussion at the NCVHS hearings conducted in 2004. In particular, committee members discussed the impact that providing electronic prior authorization may have on "removing a barrier to . . . a level playing field" in e-prescribing.[26] Pfizer is concerned that Part D plans could utilize prior authorization as a means to inappropriately steer physician decision-making by providing electronic notification that prior authorization is required, but requiring the physician to obtain such authorization via non-electronic means (e.g., faxes, phone calls). To ensure that prior authorization is not used in this

[25] Of course, any restrictions on commercial messaging of the kind described above are rooted in the clear intent of the MMA to protect patient health and safety, and the integrity of both the physician-patient relationship and the discrete prescribing "transaction" itself. This is fully consistent with Pfizer's support for the principle of free exchange of information in a variety of other contexts.

[26] Transcript, Meeting of Subcommittee on Standards and Security, NCVHS (Aug. 19, 2004).

manner, CMS should require that, in addition to the basic formulary information, Part D plans provide specific prior authorization requirements electronically, including the clinical requirements and method for receiving an approval code, to the prescriber at the point of prescription.

Full support for electronic prior authorization is not possible at this time as the complement of standards that would electronically enable the entire process are still under development. However, Pfizer believes that, as an interim measure, any proposed formulary and benefit standard should provide some degree of electronic prior authorization support. For example, the proposed NCPDP formulary standard contains message fields that could be used to provide drug-specific information on prior authorization requirements. The proposed standard also contains a resource link that could be used to provide a web link that would allow the prescriber to complete and submit a prior authorization request. While this approach would only provide an interim solution on the road to full electronic prior authorization, CMS should require that Part D plans utilize these elements of the proposed standard until full support for electronic prior authorization can be developed through pilot testing.

### E. CMS Should Develop Guidance for Updating E-prescribing Standards to Reflect Advances in Technology

As the agency undoubtedly knows, technology is not stagnant. New versions of software and hardware are constantly being developed. Even within an industry, not all stakeholders operate with the exact same technology. For example, some entities may use Microsoft Windows 98, while other may use Windows XP. Pfizer believes that e-prescribing standards will be subject to similar evolution and range of use. Consequently, CMS must develop and implement a methodology to incorporate newer versions of existing standards as they are developed without requiring the entire industry to move lockstep and without resorting to formal rulemakings for each change.

In this regard, we specifically recommend that CMS work with Standards Development Organizations (SDOs) to determine the number of versions of standards that may be accepted as "active," as well as when new versions should be adopted and when old versions should be retired. For example, when a new version of a standard is accredited by an SDO, the SDO would vote to present the new version to CMS. Instead of undertaking a formal rulemaking procedure, the new version could be presented to NCVHS for public comment and balloting in conjunction with the formal SDO balloting procedure. If both bodies approve the new version, it would be forwarded to CMS, which would announce the new version in a Federal Register notice. We recommend a similar process for retiring old versions.

## III. CONCLUSION

We appreciate the opportunity to comment on these important issues raised by the Proposed Rule, and urge you to address these concerns in a manner that fully protects the patient-physician relationship and otherwise furthers the underlying purposes of the MMA. Please let us know if we can provide you with any additional information or other assistance.

**Sincerely,**

Charles Lucas

**W. Charles Lucas**
**Senior Assistant General Counsel**

Rec 4/8/05 #13 S6

April 5, 2005

Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G, Hubert H. Humphrey Bldg.
200 Independence Ave., SW
Washington, DC 20201

**ATTN: CMS-0011-P**

**RE: Comments on Proposed Rule -- Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule**

Dear Sir or Madam:

The American Association of Nurse Anesthetists (AANA) appreciates this opportunity to comment on the proposed rule for E-Prescribing and the Prescription Drug Program (70 Fed Reg. 6256, February 4, 2005). The AANA is submitting comments in the area of Provisions of the Proposed Rule, Proposed Definitions.

The AANA is the professional association for more than 30,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists representing over 90 percent of the nurse anesthetists in the United States. Today, CRNAs are directly involved in approximately 65 percent of all anesthetics given to patients each year in the United States. CRNA services include administering the anesthetic, monitoring the patient's vital signs, staying with the patient throughout the surgery, as well as providing acute and chronic pain management services. CRNAs provide anesthesia for a wide variety of surgical cases and are the sole anesthesia providers in almost 70 percent of rural hospitals, affording these medical facilities obstetrical, surgical, and trauma stabilization, and pain management capabilities. CRNAs work in every setting in which anesthesia is delivered including hospital surgical suites and obstetrical delivery rooms, ambulatory surgical centers (ASCs), pain management units and the offices of dentists, podiatrists and plastic surgeons.

**AMERICAN ASSOCIATION OF NURSE ANESTHETISTS - FEDERAL GOVERNMENT AFFAIRS OFFICE**
**The Capitol Hill Office Building, 412 1st Street, S.E., Suite 12, Washington, D.C. 20003**
**Telephone: (202) 484-8400 ■ Facsimile: (202) 484-8408**

The AANA recognizes the need for policies and setting standards that are consistent with the Medicare Modernization Act's (MMA) objectives of promoting patient safety, quality of care, and efficiencies and cost saving in the delivery of care. For this reason, the AANA supports CMS' efforts in this area.

**PROVISIONS – II. Provisions of the Proposed Regulation, B. Proposed Definitions**

**AANA Request: That CMS, in issuing the final rule for E-prescribing and the Prescription Drug Program, maintain its current definition of "prescriber" so long as (1) the final definition recognizes States' ongoing discretion in determining which providers may be granted prescriptive authority and (2) the final definition encompasses CRNAs and other providers who are granted prescriptive authority through the State in which they practice.**

The proposed rule states, "Prescriber means a physician, dentist, or other person licensed, registered, or otherwise permitted by the U.S. or the jurisdiction in which he or she practices, to issue prescriptions for drugs for human use." (70 FR 6256, 6265, 02/4/2005) While the proposed definition of "prescriber" is technically correct, it does not explicitly reflect that providers who are not physicians, such as CRNAs, are among the "prescribers" included in the definition. It is our understanding that CRNAs would be included in the "other person licensed, registered, or otherwise permitted..." portion of the "prescriber" definition.

Currently, each State has discretion in determining which providers may be granted prescriptive authority. Many states continue to exercise this discretion by granting CRNAs prescriptive authority. The AANA requests that CMS's final definition of "prescriber" remain as proposed so long as the final definition encompasses providers, including CRNAs and others who are not physician providers, who are granted prescriptive authority through the State in which he or she practices.

We thank you for the opportunity to comment on the proposed rule. Should you have any questions regarding these matters, please feel free to contact the AANA Director of Federal Government Affairs, Frank Purcell, at 202.484.8400.

Sincerely,

Frank T. Maziarski

Frank T. Maziarski, CRNA, MS, CLNC
AANA President

cc: Jeffery M. Beutler, CRNA, MS, AANA Executive Director
Frank Purcell, AANA Director of Federal Government Affairs

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LTCPA Long Term Care Pharmacy Alliance

April 5, 2005

The Honorable Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
Room 445
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

**Re: CMS-0011-P Comments on E-Prescribing and the Prescription Drug Program: Proposed Rule**

Dear Dr. McClellan:

The Long Term Care Pharmacy Alliance (LTCPA) is pleased to submit its comments on the Centers for Medicare and Medicaid Services (CMS) Proposed Rule on E-Prescribing and the Prescription Drug Program. 42 Fed. Reg. 6256 (February 4, 2005). The LTCPA is an alliance representing the four major national long-term care (LTC) pharmacies, estimated to serve three out of every five nursing home residents and numerous other beneficiaries in institutional settings, through over 500 LTC pharmacies nationwide. In the course of that service, LTCPA and its members have developed a preeminent expertise in providing prescription drugs and related services to this particularly frail and elderly population, virtually all of whom will be affected by proposed regulations on e-prescribing.

CMS proposes to implement a set of "foundation" e-prescribing standards ahead of the statutory timeframe. However, the proposed foundation standards include the National Council on Prescription Drug Programs' (NCPDP) SCRIPT Version 5.0 which do not work in the LTC pharmacy setting. The SCRIPT standards do not accommodate the type of three-way communication that is essential to the services we provide.

Given those concerns, we have numerous comments addressing both foundation standards and the overall proposed regulation in the long-term care context, which, in turn, directly affects the health and well-being of beneficiaries who are residents of LTC facilities. We also suggest a series of proposed solutions to improve the proposed regulations to ensure that medically necessary and appropriate prescription drugs are timely and properly delivered and administered to LTC residents and related populations served by the LTC pharmacy community. We urge CMS to seriously consider the issues we raise in our comments and the solutions we propose.

Our comments are divided into three sections. In the first section, we describe LTC pharmacy and its responsibility for the needs of the residents we serve. We also explain the critical role that LTC pharmacy has come to serve in today's health care system, and the specialized services

that LTC pharmacy alone can provide. Understanding these services is important, in that the functionality and structure of any e-prescribing system must accommodate these services and ensure they are integrated into any comprehensive e-prescribing regime. Section II contains LTCPA's response to the Proposed Rule in light of these specialized services and the three-way proscribing process that occurs in the long-term care setting. Section III summarizes LTCPA's recommendations and expresses our interest in continuing to work with CMS to develop e-prescribing standards that meet the needs of Medicare beneficiaries residing in long-term care facilities and other settings.

## I. LONG -TERM CARE PHARMACY AND THE SPECIAL NEEDS OF THE RESIDENTS WE SERVE

**Nursing Home and other LTC Residents Today have Specialized Drug Therapy Needs Far Different Than the Ambulatory Medicare Beneficiary.** To address those needs, over the past 25 years the LTC pharmacy industry has emerged to serve the unique needs of the nation's most frail elderly persons. CMS, in its Part D rulemaking, has already recognized the fact that LTC pharmacy has responded to those needs through development of a sophisticated delivery system far beyond the scope of what a typical retail pharmacy provides today. Because LTC residents' needs, the services currently being provided by LTC pharmacy, and the resulting cost savings to health care delivery all factor into LTCPA's comments to the proposed regulation, we expand upon them below.

**LTC Residents Typically Need Greater Drug Therapy.** Unlike the typical ambulatory senior, residents in LTC facilities usually are older, in poorer health, and in need of greater care. A 1999 study by Bernabei *et al.* described the typical LTC resident, as follows:

- mean age of residents is 83.1 years;
- 62% of residents were admitted to the LTC facility from an acute care hospital;
- over half of LTC residents had abnormal cognitive function, and only 17% were characterized as independent or required limited assistance in performing the activities of daily living;
- residents typically had three medical conditions, with 45% having four or more and 10% having more than six medical conditions. Typical diseases included cardiovascular clinical conditions (63%), hypertension (31%), coronary artery disease (23%), and congestive heart failure (19%). Significantly, 42% of residents had dementia, and 20% were stroke victims; and
- LTC residents were taking an average of 6 drugs, with 45% taking seven or more drugs, and 20% taking more than 10 drugs. Over 50% were on some type of cardiac medication, and approximately 40% were on an analgesic.[1]

More recently, the 2000 National Medication Usage Study of 63,671 nursing home residents revealed an average of 8.07 routine medication orders per resident, with 41% receiving 9 or more

[1] *See* Bernabei, *et al., Characteristics of the SAGE Database: A New Resource for Research on Outcomes in Long-term Care*; J. 54 Gerontol. A. Biol Sci. Med. Sci. M25 (1999). At the time it was published, the Bernabie *et al.*study and the SAGE database were the only published statistics specific to long-term care structured to capture specific processes of care provided in LTC facilities. *Id.* at M29.

routine medications per day.[2] The most commonly used drug classes were antidepressants (45%), analgesics (30%), antipsychotics (24%) and anxiolytics (11%).[3] The frequency of drug usage does not reflect an overuse of medications, but rather the increased efficacy of today's more advanced medicines, and the significant improvements in quality of life that pharmaceuticals can provide to LTC residents who previously had little hope of recuperation from serious illnesses.

**LTC Residents Typically Need Different Drug Therapies Than Their Ambulatory Counterparts.** Not only are elderly LTC residents on more medications, but they require different medications and different types of mediations. More specifically, as a person ages their body processes drugs differently due to their changing metabolism and typical decreases in kidney function.[4] There has been extensive treatment in the literature describing the need for a different formulary for the elderly,[5] and companies have published specialized care guidelines documenting exactly how different drugs typically prescribed react (and interact) in these frail elderly people.[6] While these specialized formularies are often not widely known outside that segment of the medical community involved in geriatric treatment, the specifics of geriatric care are extremely important in avoiding adverse drug affects and inappropriate treatment.

In addition to differing drug needs, LTC patients often require specialized drug intake systems. One LTCPA member has estimated from their Minimum Data Set records of over 400,000 LTC residents that 9.3% of LTC patients cannot swallow and must be tube fed, and an additional 20.5% of residents have difficulty swallowing and must take their medications through capsules, liquids, injectables, or through pills that can be crushed. Oftentimes, doctors are not familiar with the specialized dosage forms that a nursing resident may need, and the pharmacy has to interact with the doctor to modify a prescription (this is but one example of why long-term care pharmacy must be integrated into the e-prescribing regime). While LTC pharmacy today is equipped to handle and manage these specialized needs, the typical retail or other pharmacy or pharmacy benefit manager is not equipped to address these concerns, or properly manage the significant drug requirements of this specialized elderly population.

**LTC Residents Receive Enhanced Drug Services.** In light of the significant patient needs noted above, both standards of care and federal and state regulations have evolved to provide LTC residents with an enhanced set of services related to their prescription drugs not provided by retail pharmacy. These services include:

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[2] *See* D.E. Tobias and M. Sey, *General and Psychotherapeutic medication Use in 328 Nursing Facilities: A Year 200 National Survey*, 16 Consult. Pharm. 54 (2001).

[3] *Id.*

[4] *See* M. Fouts, J. Hanlon., C. Pieper., E. Perfetto, and J. Feinberg,, *Identification of Elderly Nursing Facility Residents at High Risk for Drug-Related Problems,* 12 The Consultant Pharmacists 1103 (1997).

[5] *Id.; see also* M. Beers, *Inappropriate Medication Prescribing in Skilled Nursing Facilities,* 117 Annals of Internal Med. 684 (1992); A. Stuck, M. Beers, *et al., Inappropriate Medication Use in Community-Residing Older Persons,* 154 Arch. Intern. Med. 2195 (1994); M. Beers, *Explicit Criteria for Determining Potentially Inappropriate Medication Use by the Elderly,* 157 Arch Intern. Med. 1531 (1997).

[6] *See, e.g.,* Omnicare, Inc., *Geriatric Pharmaceutical Care Guidelines, The Omnicare Formulary* (2001). Omnicare is a member of the LTCPA.

1. Unit Dose and Other Specialized Drug Packaging. This packaging serves two important functions. First, the packaging allows for greater quality control of the drugs and dosages to ensure that medications are taken appropriately and without error. Second, the unit dose system provides a uniform and easily managed process for drug delivery through the central distribution point of the LTC nurse, who will actually deliver the drugs to the patient on any given day. The critical nature of this uniform distribution system throughout the facility cannot be overemphasized. LTC facility nurses face a significant challenge in distributing multiple drugs to dozens of patients each day.[7] The specialized drug packaging provided by LTC pharmacy today is a critical system in helping to reduce patient risks of receiving the wrong drugs, or the inappropriate dosages, from a nurse making delivery rounds.

2. Around the Clock "24/7" Delivery. LTC pharmacy also provides round the clock availability, either through delivery services, med-carts and emergency carts,[8] all of which assist in getting patients necessary medications in a timely manner. This service is particularly important in having intravenous medications available for LTC residents, so that they do not have to be transported to a hospital for treatment. It is critical for CMS to recognize the enormous cost savings to the health care system just from this single service.

3. Consultant Pharmacist Services. In addition to providing the drugs, LTC pharmacy also provides a set of services through Consultant Pharmacists, who are able to review and assist in patient drug care. These services include retrospective drug regimen reviews, as required by law,[9] and prospective drug regimen reviews to screen for medical appropriateness of the prescribed drugs and for inappropriate drug interactions.[10] LTC pharmacists also counsel patients, provide information and recommendations to prescribers and caregivers, review patients' drug regimens, present in-service educational programs, and oversee medication distribution services -- all in addition to providing medication. LTC pharmacists also provide a wide range of other primary care services to seniors, including pain management counseling, pharmacokinetic dosing services, intravenous therapy, nutrition assessment and support, and durable medical equipment assessments and support. In this way, LTC pharmacy is the principal defense against medical errors and ensures the highest quality of patient care.

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[7] *See also* R. Tamblyn, *Medication Use in Seniors: Challenges and Solutions*, 51 Therapie 296 (1996). Tamblyn aptly notes that [h]ealth care system policy and practice can have a substantial impact on the drug utilization among seniors." *Id.* at 275. "Although regulatory changes are made in [governmental] drug plan policies to control costs, there is virtually no information on the impact of drug policy interventions on drug utilization patterns and patient outcomes." *Id.* at 276.

[8] Med-carts and emergency carts are pre-positioned medicines provided to the LTC facility for emergency uses. Typically, several thousand dollars of drugs are stored in such carts, which are only used when a patient emergency arises.

[9] 42 C.F.R. 468.60(c).

[10] M. Dashner, S. Brownstein, K. Cameron J., Feinberg, *Fleetwood Phase II Tests A New Model of Long-term Care Pharmacy,* 15 The Consultant Pharmacist 989 (Oct. 2000). The Fleetwood Phase II project also documented the benefits of early pharmacist intervention on identification of high risk patients, interaction with the prescribing doctor, and development of care plans.

Critical for the provision of these important services is the need for the dispensing pharmacy and its consultant pharmacists to have a complete and accurate understanding of the patient's medical conditions, and, more importantly, current drug utilization.[11] Given current technological and other limitations, the only way in which appropriate drug reviews can be conducted, particularly on a prospective (rather than retrospective) basis is for there to be a single dispensing pharmacy for any given patient.[12] Stated differently, the prerequisite to prospective drug regimen review and medication interaction screenings is that there be a single pharmacy from which the patient's medications are dispensed, which has complete knowledge of the medications that a patient is on at any given time. Without that single source, there is no way for the pharmacy or pharmacist to know the actual drug intake that the patient is consuming, or to monitor for contraindications, inappropriate drug interactions, drug abuse, or inappropriate utilization of prescriptions. The value of these screening services is significant. Bootman *et al.* estimated that Consultant Pharmacist intervention saves $3.6 billion (in 1997 dollars) in avoided drug related problems.[13]

Bootman *et al.* explained their finding that drug-related problems in the LTC context ($4.6 billion with consultant pharmacists, as opposed to $8.2 billion without their services) were a third higher than those he had previously found in the ambulatory setting:

> First, nursing facility residents consume, on average, a greater number of prescription medications, thus increasing the potential for [drug related problems, or] DRPs. Additionally, in contrast to their ambulatory counterparts, nursing facility residents are placed at higher risk of DRPs because of the physiological effects of aging that alter the ability to metabolize certain drug products. Finally, another factor leading to the greater cost of drug-related morbidity and mortality is that once a DRP has occurred in the nursing home patient, there is a greater intensity of care required to treat the DRP. This could be the result of a more severe reaction experienced by the frail elderly or the higher costs of care that occur within the institutional setting.[14]

**The Vast Majority of LTC Residents Currently Receive Prescription Drug Benefits under Medicaid, and, As Dual Eligibles, Will Comprise a Significant Percentage of Enrolled and Active Part-D Beneficiaries In The Coming Years.** A recently completed Lewin Group study on "Payer -Specific Financial Analysis of Nursing Facilities," published in March, 2002, indicated that 66% of LTC residents are Medicaid beneficiaries, 12% are Medicare beneficiaries (receiving specific Medicare pharmacy benefits, for example, within their "first 100 days") and the remaining 22% receive insurance benefits or are "private pay" patients. These findings are consistent with

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[11] Tamblyn, *supra* at note 6 at 275 (noting that risk of inappropriate drug prescriptions could be reduced 20 to 30 percent by ensuring that primary physicians and pharmacists have "better access to information about all drugs prescribed to patients") (emphasis added).

[12] While current law only requires retrospective drug regimen reviews, the advantages of prospective drug screening are documented in the literature. *See, e.g.*, Dashner, *supra* at note 10.

[13] *See* J.L. Bootman, D.L. Harrison, E. Cox, *the Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities*, 157 Arch. Intern. Med. 2089 (1997). Bootman *et al.*'s analysis did not even account for prospective drug regime reviews which are conducted by many LTC staff pharmacists today. *Id.* at 2096.

[14] *Id.* at 2095.

both the National Health Expenditures analysis (CMS Office of the Actuary) and the National Health Expenses Chartbook compiled by the Agency for Healthcare Research and Quality. The National Health Expenses Chartbook also indicates that between 1987 and 1996 the number of LTC residents receiving prescription drugs outside of a Medicare or Medicaid benefit declined from 33.1% to 24.4%. Data provided by LTC operators from approximately 3,000 facilities suggest that within six months of entering a LTC facility, approximately 80% of private pay patients become Medicaid eligible and that by the end of a year, 99% of those residents entering as "private pay" patients become Medicaid eligible.

Thus, it is important for CMS to recognize that the vast majority of LTC residents receive Medicaid prescription drug benefits which include access to "medically necessary" prescription drugs. Virtually all of these so-called "dual eligibles" will be auto-enrolled into the Part D program, and will, likely be the most significant cohort of prescription consumers within the first few years of the Part D program. Thus, it is particularly important in this rulemaking that CMS focus upon this class of beneficiaries, and the pharmacies and doctors that provide prescription drugs to them, to ensure that a functional system is implemented.

**LTC Pharmacy is Different from Retail Pharmacy**. CMS must also recognize that LTC pharmacy is different from the retail pharmacies that are likely to join PDP plans' networks, or those pharmacies contemplated by the MMA as serving the ambulatory Medicare population that will serve as the backbone of the PDP network.[15] In the retail pharmacy setting, a prescriber transmits a prescription directly to the pharmacy on behalf of the Medicare beneficiary. The prescription is filled by the retail pharmacy, (after checking on the enrollment and benefit status of beneficiary, and charging appropriate co-pays,) and delivered to the beneficiary.

By contrast, the long-term care pharmacy must interact not only with the prescriber, but also with the nursing home in which the beneficiary resides. For example, in most cases, the prescription is transmitted to the long-term care pharmacy by nursing home staff. The prescription is then delivered to the nursing home facility, not to the individual beneficiary. The long-term care pharmacist relies on medication records and medical records at the nursing home to check on drug interactions and other contraindications. The nursing home relies on the long-term care pharmacy for specialized packaging, prompt delivery, and the specialized services of its consultant pharmacist.

In addition to dispensing medications, the long-term care pharmacy represents the beneficiary in coverage issues and appeals. Currently, under Medicaid, long-term care pharmacists engage in adjudication with fiscal intermediaries for prior authorization and appeals processes for dual-eligible beneficiaries. As of January 1, 2006, Medicare beneficiaries or their physicians must request coverage determinations from PDPs or appeal those coverage determinations. If a Medicare beneficiary appoints the long-term care pharmacist as his or her representative for grievance, coverage determination, or appeals processes, the long-term care pharmacist also will need to communicate with the PDP to request coverage determinations and, possibly, appeal negative coverage determinations. These responsibilities require access to beneficiaries' medication history and medical history and interaction with staff at the nursing home and the prescribing physician in order to document the need for a particular medication.

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[15] CMS has previously recognized this distinction in its 2002 rulemaking on the ten-proposed discount drug card program . *Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative*, 67 Fed. Reg. 56,617, 56,640 (Final Rule, Sept. 4, 2004).

In summary, long-term care pharmacies have responsibilities for the prescription drug needs of residents of long-term care facilities that are qualitatively different from those of retail pharmacies. These special responsibilities are reflected in the contracts that long-term care facilities enter into with nursing homes, and illustrate the three-way relationship between the prescriber, the nursing home, and the long-term care pharmacy that must, in turn, be reflected in the e-prescribing process.

## II. Comments on the Proposed Regulation

### A. The Proposed Regulation Does Not Account for The "Three-Way Transaction" Which Is A Part of Every Long-Term Care Pharmacy Prescription Cycle

Before addressing the specifics of the proposed regulation, LTCPA would like to preface its comments by noting that the Proposed Rule does not address the specific locations in which e-prescribing occurs. As long-term care pharmacy providers, our comments are based on our experience as one component of a prescribing process that also includes physicians and nursing home administrators and staff. At each point in the prescribing process, these three entities will interact. Particularly given the anticipated predominance of dual eligibles in the Part D program, and the prevalence of those beneficiaries in long-term care facilities, we believe CMS should expressly recognize and accommodate the needs of these beneficiaries in e-prescribing regulations.

Under the new Medicare prescription drug benefit, physicians will transmit prescriptions to the long-term care pharmacy through the nursing home staff, and the long-term care pharmacy will interact with the nursing home staff to check medication history and medical history records that are kept in the nursing home. Physicians will initiate prior authorization and other coverage determination requests and also can file appeals on behalf of their patients, and these determinations will be communicated to the long-term care pharmacy by the nursing home staff. If the long-term care pharmacist is designated to represent the beneficiary, these requests can be initiated by the long-term care pharmacist on behalf of the Medicare beneficiary, and the long-term care pharmacist will relay the outcome of these requests to both the nursing home and the prescribing physician so that beneficiaries' records can be updated.

The nature of this three-way transaction makes the setting in which e-prescribing takes place an important consideration in CMS' design of e-prescribing standards. In evaluating its proposed regulation, therefore, we strongly urge CMS to depart from a "one size fits all" approach, and to recognize explicitly in its proposed regulation that there needs to be unique and different e-prescribing standards for the long-term care community that function within the three-way transaction construct. We hope that our comments below provide insight for the agency into the unique e-prescribing issues that we face as one party to these three-way e-prescribing transactions, and offer our assistance as CMS develops e-prescribing standards that reflect the needs of prescribers, nursing homes, and long-term care pharmacies.

## B. CMS' Proposed SCRIPT "Foundation" Standard Does Not Work for LTC Pharmacy Because LTC Pharmacy Needs an E-Prescribing Standard That Accommodates Three-Way Communication Between the Physician, Nursing Home, and LTC Pharmacy

CMS requests comment on whether a set of "foundation" standards are ready to be implemented ahead of the statutory timeframe, and whether these standards should only apply to Part D eligible individuals enrolled in Part D plans. Section 1860D-4(e)(4)(C)(i) of the Act permits an exception to the pilot testing of standards when the Secretary determines that there is "adequate industry experience" with the standards. After receiving input from various industry entities, CMS proposes to forego pilot testing of the NCPDP's SCRIPT, Version 5.0 (except for the Prescription Fill Status Notification Transaction and its three business cases) and Telecommunication Standard Guide, Version 5.1 and implement them as "foundation" standards ahead of the statutory timeframe.

Although some retail pharmacies may have adequate industry experience with these foundation standards, LTCPA does not believe that the real-world functionality of SCRIPT has been well tested. SCRIPT communicates only between two healthcare entities, the prescriber and the pharmacy. This rudimentary communication capability does not work for LTC pharmacies because the nature of our prescribing process necessitates a three-way communication between prescribers, nursing homes, and LTC pharmacies.

SCRIPT reflects a prescribing physician-to-pharmacy communication, not the three-way communication path that occurs in a long-term care setting. For example, SCRIPT does not support a refill request from a nursing home to a LTC pharmacy, nor does it support an order discontinuation request from the nursing home to the LTC pharmacy. In the long-term care setting, the nursing home and the LTC pharmacy work in tandem and information systems for prescription drugs must include the nursing home in the e-prescribing process.

In addition, nursing homes receive the majority of their admissions from hospitals., and SCRIPT does not capture the robust information transfer that currently occurs between the hospital, physician, nursing home, and LTC pharmacy. A newly admitted LTC resident coming from a hospital stay is likely to have greater co-morbidities, more complex drug regimens, and a need for more complex medications, including infusion therapy. In order to provide proper pharmaceutical care, a prescriber and an LTC pharmacist must communication with other healthcare providers serving the resident. Hospitals and other health care environments use Health Level 7 (HL-7) which allows this type of communication, and SCRIPT is not compatible with HL-7.

Therefore, LTCPA opposes the use of SCRIPT as a foundation standard. Instead, we propose that CMS revise its approach to e-prescribing standards development, including foundation standards, to incorporate the type of three-way communication that is essential in the long-term care setting.

With respect to CMS' request for comments on its interpretation of Congressional intent for the scope of e-prescribing standards, LTCPA supports CMS' view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans. While some may argue that this view is unnecessarily narrow and that e-

prescribing standards should be required for a broader set of transactions, LTCPA believes the narrow interpretation is the correct understanding of Congress's intent. Developing and implementing e-prescribing standards within the Part D prescription drug benefit is an enormous challenge for the agency, plans, prescribers, and pharmacies, including LTC pharmacies, and is best accomplished by confining these efforts to the Part D Medicare program. LTCPA's member companies want to be prepared to engage in e-prescribing for Part D eligible individuals in a range of settings, including long-term care facilities, assisted living facilities, and intermediate care facilities for the mentally retarded (ICF/MRs). Rather than over-extending the application of these standards, LTCPA believes that CMS should devote its resources to provide technical assistance and monitoring of the implementation of e-prescribing standards within the Part D program.

## C. Pilot Testing of Initial Standards Should Include Long-Term Care Pharmacies Participating in PDP Networks

In order to conduct pilot testing of initial standards for an electronic prescription drug program prior to promulgation of the final uniform standards, the Secretary is required to enter into agreements with physicians, physician groups, pharmacies, hospitals, PDP sponsors, MA organizations, and other appropriate entities under which health care professionals electronically transmit prescriptions to dispensing pharmacies and pharmacists in accordance with such standards. (Section 1860D-4(C)(iii)). Prescriptions for long-term care residents are written by the physician and sent to the nursing home and then transmitted to the long-term care pharmacy, which, in turn, communicates with the nursing home and prescribing physician. Pilot testing of these initial standards must, therefore, occur in settings where this three-way transaction is integral to e-prescribing processes.

LTCPA believes that the timeframe for the implementation of pilot testing is too short, and must be extended. If CMS intends to implement pilot testing on January 1, 2006, the agency should implement a staggered implementation in which initial standards can be pilot tested as they are developed with input from all parts of the industry. LTC pharmacies would be logical sites for early pilot testing. Moreover, pilot testing in LTC pharmacies will provide the agency with information on the application of these initial standards to entities involved in complex prescribing procedures involving multiple entities as well as information on how e-prescribing standards are working with an institutionalized population of dual-eligible beneficiaries.

LTCPA recommends that CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies, and that these standards are working in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside. CMS's evaluation of the pilot testing must also specifically address the experience of physicians, nursing homes, and long-term care pharmacies in its report to Congress on the outcome of the pilot testing.

## D. Preemption is Not Appropriate Until CMS Resolves Issues Related to Existing DEA and Other State Pharmacy Regulations

CMS proposes that the e-prescribing standards it develops will preempt State laws when the state law or regulation: (1) is contrary to the standards or restricts the ability of CMS to carry out e-prescribing in the Part D program; and (2) pertains to the electronic transmission of medication history and of information on eligibility, benefits, and prescriptions with respect to covered Part D drugs. The State law or regulation would have to meet both of these requirements before it is preempted by Federal electronic prescription program drug requirements adopted through rulemaking.

LTCPA believes that it is important to maintain state pharmacy regulations that impact e-prescribing standards until CMS has worked through the issues it identifies in the proposed regulation. For example, CMS acknowledged during the Special Open Door Forum on the Proposed Rule that it is still attempting to negotiate with the DEA on conforming Medicare's Part D e-prescribing standards with DEA regulations for prescriptions for controlled substances. LTCPA recommends that CMS and the DEA resolve this issue prior to CMS promulgating final e-prescribing standards involving controlled substances. LTCPA also recommends that CMS work with states and other insurers that require non-electronic signatures, so that Federal e-prescribing standards do not put long-term care and other pharmacy providers in the position of needing to comply with two sets of standards for prescriptions for controlled substances.

CMS also should not subject to preemption state pharmacy regulations that require the prescription to be first transmitted to the pharmacy. In the long-term care setting, physicians and nursing home staff do not necessarily know a resident's pharmacy benefits and eligibility coverage, which may change based on level-of-care. The long-term care pharmacy industry standard is for the long-term care pharmacies to keep this information. Under Part D, it will be important for long-term care pharmacies to have this information in real time so that they can meet the coordination of benefits requirements for Medicare Part A, B, and D.

Therefore, LTCPA believes it is essential that Federal e-prescribing standards not preempt state regulations that require a prescription to be submitted to the pharmacy by the prescriber (or by the prescriber via the nursing home), rather than first submitted to a pharmacy benefit manager and then to the pharmacy. Long-term care pharmacies operate under this system in states with this pharmacy regulation, and believe that this procedure will help to ensure timely dispensing of prescription drugs for beneficiaries residing in long-term care facilities. LTCPA recommends that state regulations that require a prescription to be submitted to the pharmacy first not be preempted by CMS' Medicare E-Prescribing Standards.

## E. Anti-kickback Statute Safe Harbor is Needed as Guidance for LTC Pharmacies

As CMS notes in the Preamble to the Proposed Rule, Section 1860D-4(e)(6) of the MMA requires the Secretary to promulgate regulations that provide for a safe-harbor under the Anti-kickback statute and an exception under the physician self-referral (Stark) statute for certain non-monetary remuneration (in the form of hardware, software, or information technology and training services) related to e-prescribing information technology items and services. LTCPA recommends

that CMS and the Secretary request the Office of the Inspector General to promulgate these regulations for PDP sponsors for pharmacists and pharmacies participating in their networks as quickly as possible (but surely no later than December 1, 2005, so that they can be used when the Part D program begins on January 1, 2006) so that long-term care pharmacies will have guidance on the types of non-monetary remuneration that are not subject to sanctions under the Anti-kickback statute.

LTCPA anticipates that there will be circumstances in which PDP plans or the pharmacies themselves may be interested in providing non-monetary remuneration in the form of hardware and software (e.g. pre-programmed PDAs for prescribing physicians) and training for prescribers and nursing home staff related to e-prescribing. A safe-harbor under the Anti-kickback statute will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration that are acceptable under the statute.

## F. CMS' Proposed Incremental Approach to Standards Development Is Flawed And Contrary to Law; All Standards Should be Subject to Notice of Proposed Rulemaking

CMS requests comments on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. LTCPA has serious reservations about CMS' proposed "incremental approach" to adopting final uniform standards for e-prescribing, and is particularly disturbed that CMS would consider requiring any additional standards without a Notice of Proposed Rule Making (NPRM) process. Any standard, including the foundation standards proposed in this rule, represents a substantive requirement for Part D plans and, as standards for electronic e-prescribing, will impact the work of prescribers and providers, including long-term care pharmacies. Only formal rule-making processes will ensure that these entities will have an opportunity for notice and comment. The federal Administrative Procedures Act, 5 U.S.C. § 501, *et seq.*, requires no less.

Long-term care pharmacies now serve the vast majority of Medicare beneficiaries in long-term care facilities and our input regarding adequate industry experience must be factored into CMS' assessment of industry experience with any proposed e-prescribing standards. LTCPA supports the standards design criteria outlined in the MMA, particularly the requirement that standards not impose an undue administrative burden on prescribing healthcare professionals and dispensing pharmacies and pharmacists. We believe that the e-prescribing practices in place throughout our member companies help to prevent adverse drug events (ADEs) for the residents of long-term care facilities we serve. Because we serve nursing homes on a 24/7 and emergency delivery basis, instant connectivity between the health care provider, the nursing home facility, the pharmacy and the PDP plan is a goal we support. However, e-prescribing standards must not unduly burden prescribers, nursing homes, or long-term care pharmacies. Therefore, LTCPA recommends that the third proposed criteria for the development of e-prescribing standards be amended as follows: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard." We believe this recommendation conforms with CMS' interest in proposing standards that are "vendor neutral" and will ensure that final e-prescribing standards will work for LTCPA members and other long-term care pharmacies.

Any future standards should be subject to formal agency rulemaking, even if CMS decides to forego pilot testing because of adequate industry experience. The National Committee on Vital and Health Statistics (NCVHS) and standards setting organizations may make recommendations to CMS on e-prescribing standards, but only CMS can promulgate standards through formal rulemaking. Section 1860D-4(e)(4)(B) requires the NCVHS to make recommendations for standards, in consultation with standard setting organizations and other entities, to CMS after consultation with organizations and entities. Section 1860D-4(e)(4)(A) requires the Secretary to *take these recommendations into consideration when developing, adopting, recognizing, or modifying* initial uniform standards, which then are to be pilot tested prior to the agency issuing final standards. The only exception to this process, is that the Secretary, after consultation with standard setting organizations and industry users, may decide not to pilot test standards for which there already is adequate industry experience. The exception provided by Congress applies to the pilot testing requirement, not the rule-making requirement. Clearly, Congress intended for CMS to promulgate rules for the adoption of e-prescribing and for other bodies, including NCVHS, to serve in an advisory capacity, not a rule-making capacity.

## G. Issues Related to the Electronic Prescription Drug Program

### 1. Provider and Dispenser Identifiers

LTCPA will cooperate with efforts by CMS to properly identify dispensers. With regard to unique identifiers for prescribers and dispensers in e-prescribing transactions, LTCPA would support either a National Provider Identifier (NPI), should it become available by January 2006, or the continued use of the NCPDP Provider Identifier Number. At present, NCPDP's Provider Identifier Number can identify long-term care pharmacies with the suffix it uses in the Dispenser Identifier. Adoption of NPI for e-prescribing in all likelihood will be a longer process, however LTCPA will work with CMS to implement the NPI should the agency adopt it. In order to facilitate CMS' task of accelerating the enumeration of all providers, LTCPA member companies are willing to provide a listing of long-term care pharmacy providers serving Medicare beneficiaries to the agency.

### 2. Formulary and Medication History Standards

Although the NCVHS has recommended that CMS use the RxHub protocol as a basis for rapidly developing an NCPDP standard for formulary and medication history, LTCPA opposes any approach that precludes timely three-way interactions between prescribers, nursing homes, and long-term care pharmacists in the e-prescribing process. We believe certain features of RxHub, e.g. automatically sending a non-formulary prescription back to the prescriber, precludes the involvement of the long-term care pharmacy or nursing home in this process. If, for example, a Medicare beneficiary designates a nursing home administrator or long-term care pharmacist to represent him in coverage determinations requests, these entities must know about the drug that the physician is attempting to prescribe so that they can request a prior authorization on behalf of the beneficiary.

CMS proposes a set of characteristics it considers critical for formulary, benefit, and medication history messaging and requests comments on whether these characteristics should be considered for adoption as foundation standards. LTCPA recommends that the critical characteristics for formulary and benefit data standards be amended to reflect the three-way

transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

Moreover, within the long-term care setting, dual-eligible beneficiaries are not subject to premium and co-pay provisions, and it will be important to distinguish these individuals in the e-prescribing process. LTCPA proposes that the standards for formulary and benefit data be amended to include reference to "long-term care dual eligible resident" and "long-term care non-dual eligible resident" categories so that long-term care pharmacies will be able to quickly identify dual eligible residents who are not subject to premiums and co-payments and other residents of long-term care facilities.

### 3. Drug Information

Residents of long-term care facilities have complicated drug regimens often consisting of 8 or more drugs per day. Electronic prescription drug information that includes information on drug-drug interactions, warnings or cautions, and, when indicated, dosage adjustments is crucial in the long-term care pharmacy setting. Long-term care pharmacies dispense medications on a 24/7 and emergency basis to nursing homes. Having access to this information in electronic format will assist physicians in appropriately prescribing medications, as well as assist long-term care pharmacies to efficiently and safely dispense prescriptions to Medicare beneficiaries in compliance with the Nursing Home Reform Act of 1987 and other industry standards of care.

### 4. Medical History

CMS notes in the Preamble to the Proposed Rule that NCVHS has not yet provided recommendations on standards for medical history. LTCPA stands ready to work with NCVHS to provide recommendations to CMS on e-prescribing standards for medical history. In the long-term care setting, medical records for Medicare beneficiaries, like all other residents, are located at the nursing facility, not in the physician's office. Accurate, timely, medical histories are essential for long-term care pharmacies to dispense medications to residents of long-term care facilities. Ideally, medical history e-prescribing standards will be interoperable with electronic medical records (EHRs). LTCPA believes that these e-prescribing standards should be subject to rulemaking in order to assure that they, too, will be interoperable with future EHR standards.

## H. Internal E-Prescribing Transactions Should Not Be Subject to Standards for Prescription Communications Within Their Enterprise

CMS has asked whether any standards it adopts for prescription communications should be required for internal as well as external transactions. LTCPA agrees with NCVHS' recommendation to CMS that organizations, including long-term care pharmacies, that conduct e-prescribing transactions internally should not be required to convert to the adopted standards for prescription communications within their enterprise. As we noted, LTC pharmacies engage in specialized dispensing services (e.g. emergency deliveries) not required of retail pharmacies. CMS has recognized these specialized services in the guidance it has developed for long-term care under the Part D benefit. Because our services are specialized, our internal communications reflect the provision of those specialized services. LTCPA is concerned that if standards for prescription communications are applied within an entity that our communication needs will not "fit" a standard

prescription communications template. Therefore, LTCPA recommends that e-prescribing standards only apply to external communications.

## I. New Versions of E-Prescribing Standards Should Be Subject to Formal Rulemaking

As noted above, LTCPA is concerned about the process by which standards will be updated, once adopted, and new versions developed and urges CMS to make new or updated standards subject to formal rulemaking. CMS is proposing to use an incorporate by reference update approval process in which CMS will publish an amendment to a standard in the Code of Federal Regulations in the Federal Register. If the updates are technical in nature (e.g. correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction), CMS proposes that the Secretary consider waiving notice and comment. In this case, compliance with an earlier version or the new version would constitute compliance with the standard. If the updates are substantive (e.g. a new function is considered necessary for an e-prescribing transaction), CMS proposes to modify the required standards through notice and comment rulemaking. CMS proposes to base its determination on whether to waive notice and comment on the significance of any corrections or revision and whether the newer version is "backward compatible" with the previously adopted version. According to CMS, "backward compatible" means that the newer version retains the full functionality of the previously adopted version that had been adopted through rulemaking.

LTCPA disagrees with NCPDP's position that the decision to change a standard is dependent on the standards setting organization and should not be constrained by the federal standard version naming process. The NCPCP vetting process is a consensus process, but individual members of the NCPDP may have specific business practices which will be negatively affected by allowing NCPDP to determine the timing and release of new versions of Federal e-prescribing standards. Apparently, NCPDP is interested in avoiding the formal rulemaking process when introducing new versions of a standard. This is not acceptable to LTCPA members.

LTCPA urges CMS to subject all updated and newer versions of e-prescribing standards to the NPRM process. Only by having an opportunity to formally comment on updated and newer versions of Medicare e-prescribing standards will LTCPA be assured that the needs of prescribers, nursing homes, and long-term care pharmacies will be met.

## III. Conclusion

In summary, LTCPA recommends that:

- CMS not use SCRIPT as part of its "foundation" standards for e-prescribing within the Medicare prescription drug program because SCRIPT does not accommodate LTC pharmacies' need for a set of foundation standards that reflect the three-way communication that is essential in a LTC setting.

- CMS adopt the view that Congress intended to confine the application of e-prescribing standards only to information regarding Part D eligible individuals enrolled in Part D plans,

and, accordingly, implement these standards only for Part D eligible individuals enrolled in Part D plans.

- CMS pilot test initial standards during the 2006 calendar year in a sample of long-term care pharmacy settings in order to assure that the standards do not impose an undue administrative burden on prescribing health care professionals and dispensing pharmacies and that these standards work in institutional settings where substantial numbers of Medicare dual eligible beneficiaries reside.

- CMS include in its report to Congress, an evaluation of the pilot testing that specifically addresses the experience of physicians, nursing homes, and long-term care pharmacies.

- CMS resolve its issue with the DEA regarding DEA regulations for non-electronic signatures for prescriptions for controlled substances prior to promulgating final e-prescribing standards.

- CMS not subject to preemption state regulations that require a prescription to be submitted to the pharmacy by the prescriber first rather than to a pharmacy benefit manager.

- CMS urge the Secretary to quickly promulgate a safe-harbor to the Anti-kickback statute that will provide guidance to PDP plans and long-term care pharmacies on the types of non-monetary remuneration related to e-prescribing information technology items or services that are acceptable under the statute.

- CMS amend its e-prescribing standards to include: "The standard is recognized by key industry stakeholders, *including long-term care pharmacies*, as the industry standard"

- CMS subject any e-prescribing standards to formal agency rulemaking.

- CMS amend its critical characteristics for formulary and benefit data standards to reflect the three-way transactions for long-term care beneficiaries as follows: "The standards permit operation of three-way transactions between physicians, nursing home staff, and long-term care pharmacies."

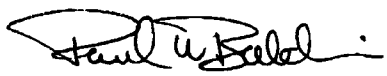
- CMS add categories to distinguish long-term care dual eligible and non-dual eligible beneficiaries to its e-prescribing formulary standards.

- CMS apply e-prescribing communication standards to external transactions only and not communications within an entity.

- CMS subject all updated and newer versions of e-prescribing standards to formal agency rulemaking.

LTCPA looks forward to working with CMS in developing Part D e-prescribing standards that work for prescribers, nursing homes, and long-term care pharmacies in meeting the prescription drug needs of Medicare beneficiaries. We would be pleased to meet with CMS staff involved in the development of these standards to further articulate our comments, and also look forward to participating in CMS' plans for piloting the initial e-prescribing standards.

Sincerely,



Paul Baldwin, Executive Director

biogen idec

Mark McClellan, M.D., Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-0011-P**
**Medicare Program; E-Prescribing and the Prescription Drug Program**

Dear Dr. McClellan:

Biogen Idec appreciates the opportunity to offer its comments to the proposed rule adopting standards for an electronic prescription drug program under Title I of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA). We are a global leader in biotechnology headquartered in Cambridge, Massachusetts with centers of excellence in San Diego, California and Cambridge. Our products and development programs address a variety of key medical needs in the areas of oncology, neurology, dermatology and rheumatology.

Biogen Idec has reviewed and generally concurs with the July 22, 2004 written comments of the American College of Physicians,[1] particularly with respect to the potential for electronic systems to inappropriately guide physician treatment decisions, the need for prior authorization submission capability, and the concern that formulary, cost, and copayment information be accurate and up-to-date. More specifically:

- The treating physician is in the best position to consider the scientific evidence and his/her knowledge of the patient's medical history in selecting the most appropriate therapy. The standards should enable physicians to select from among all potential therapies (rather than solely from formulary products), and to direct the active ingredient, dosage, formulation, and other specific instructions that may apply to a particular patient;
- For prescribed products that are not on a plan's formulary, the e-prescribing system should direct the physician to potential formulary-listed alternatives, as well as provide message instructions on exception or appeals procedures. The MMA provides exception and appeals mechanisms for instances in which a physician determines that a formulary product cannot be substituted for a prescribed non-formulary therapy; electronic prescribing standards should enable rather than thwart exercise of this important beneficiary protection. The MMA requirement for e-prescription standards on medical history information related to a Part D drug appears designed to streamline prior-authorization and

[1] http://www.acpoline.org/hpp/e-prescribe.pdf

exception/appeal processes rather than to require maintenance and dissemination of more general electronic medical histories;

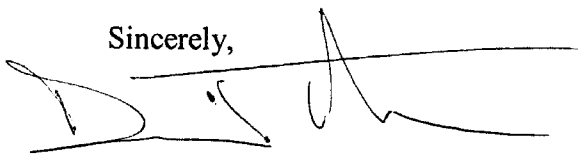
- As the ACP noted, an electronic prescription system will not provide significant benefit to physicians unless it streamlines the prior authorization process into a real-time online adjudication. Prior authorization can be a valuable tool in ensuring appropriate utilization, but can also be used as a hurdle requiring significant provider telephone intervention, additional paperwork, and other tactics to discourage providers from prescribing particular therapies. Most prior authorization requirements contain specific conditions that must be met for coverage of the prescribed therapy. Electronic physician certification of compliance or non-compliance with those conditions (at initial prescription or in response to a denial) should be worked into the messaging capabilities of electronic systems at the start of the pilot program to ensure physician participation and accurately gauge satisfaction.
- Biogen Idec generally supports electronic prescription systems that provide physicians with information on the formulary status, cost, and copayment applicable to a prescribed product. The ACP indicated that many physicians would work toward choosing therapies, in part based upon the cost to the beneficiary. We urge CMS to ensure that the standards are implemented to ensure that this information is accurate and complete for the particular beneficiary. The following examples illustrate potential pitfalls in utilizing general PDP information rather than beneficiary-specific information:
    - For a patient with a chronic debilitating condition, biological X costs $1,000 per month and is tiered for 50% copayment; biological Y costs $1,250 but is tiered for a 20% copayment. The patient and physician are frustrated and wish to appeal. They are told that formulary tier decisions are subject to appeal, except for biologics. Accurate beneficiary-specific information could alleviate frustrations:
        - If the beneficiary has already exceeded or come to close to the out-of-pocket expense maximum, there is, in fact, no difference in cost sharing percent between the therapies. Catastrophic coverage kicks in and the statutory 95% benefit controls for non-low-income beneficiaries.
        - For long-term therapies such as biologics for chronic debilitating conditions, the difference between a 50% copayment and a 20% copayment is simply a matter of whether the patient pays higher amounts for a shorter period of time or lower amounts for a longer period of time. The beneficiary will, over the long-term, pay slightly less for the less expensive therapy regardless of tiering. This is not intuitively obvious from a decision field that does not incorporate the out-of-pocket maximum calculation for a beneficiary.

- A physician prescribes a $500/month pharmaceutical that generally contains a 25% copayment. The physician believes that the beneficiary cannot afford the copayment, but lower-cost alternatives do not exist.
    - Has the electronic prescribing system maintained up-to-date information on the beneficiary's out-of-pocket expenditures to date? Is there messaging capacity to direct the beneficiary to any non-profit organization that might offer cost sharing assistance? Unless the cost and copayment data is complete and captures the beneficiary's complete plan experience, physicians may make compromise medical decisions based upon faulty financial data.

- It appears that the current systems utilizing NCPDP standards do not always contain up-to-date information on formulary changes. A system that generates erroneous information on formulary inclusion or exclusion may prove more frustrating for providers and patients than the current paper script system. Similarly, Biogen Idec is concerned that this potential shortcoming in the electronic system may have the effect of misleading patients and providers on coverage of newer therapies.

Biogen Idec supports CMS in its first steps to implement uniform standards for e-prescribing that meet the MMA goals of patient safety, quality of care, and efficiencies for cost savings in care delivery. As always, we appreciate your thoughtful consideration of our comments and are available to answer any additional questions you may have.

Sincerely,



David V. Foster
Vice President, Government Relations
Biogen Idec

American Medical Association
Physicians dedicated to the health of America

**Michael D. Maves, MD, MBA**
Executive Vice President, CEO

515 North State Street
Chicago, Illinois 60610

312 464-5000
312 464-4184 Fax



April 5, 2005

Mark B. McClellan, MD, PhD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

**Re: CMS-0011-P Medicare Program: E-prescribing and the Prescription Drug Program NPRM (42-CFR Part 423)**

Dear Dr. McClellan:

The American Medical Association (AMA) appreciates the opportunity to submit comments regarding the Center for Medicare and Medicaid Services (CMS) proposed rule on E-prescribing and the Prescription Drug Program, 70 Fed. Reg. 6256 (February 4, 2005).

**Current E-Prescribing Environment**

Although the concept of electronic prescribing (e-prescribing) appears simple, broad scale electronic prescribing as defined in the Medicare Prescription Drug Improvement and Modernization Act (MMA) barely exists in the ambulatory setting. Some hospitals and large practices can electronically communicate with on-site pharmacies via closed systems, but two-way, interoperable, and secure external systems currently are used only in extremely limited circumstances. Because much of the technology developed to date has been delivered at the desktop for hospital facilities and large group practices, there needs to be more focus on incorporating the specific needs of independently practicing physicians. Standards for advanced e-prescribing systems with "roaming" or wireless capabilities are also needed. Development of a single set of standards appropriate for all health care delivery situations will be a significant undertaking.

The AMA recently conducted a survey with Forrester entitled "Physicians' Use of Information Technology." The results of the survey indicate that implementation of e-prescribing in physicians' practices is currently very low. The following are responses to the question "Has your medical practice implemented an electronic prescribing system?"

- 8.6% reported that their practice has implemented an electronic prescribing system, but only on a limited scale.
- 11.7% reported that they have implemented an electronic prescribing system throughout the practice.
- 14.2% reported that they have not implemented an electronic prescribing system, but have investigated and tested some systems.
- 62.5% reported that they have not investigated an electronic prescribing system for their practice.
- 2.9% reported that they don't know if their practice has implemented an electronic prescribing system.

In response to a related question from the above results "If no, why not?" the following was found:

- 19.8% reported it was due to the high price of e-prescribing products.
- 11.7% reported that technology alternatives do not provide a measurable or justifiable improvement over existing methods.
- 6.7% reported that implementing new e-prescribing products requires extensive resources (e.g., personnel time, cost, etc.).
- 5.5% reported that it was because physicians resist new technologies.
- 5.4% reported that the current hardware/software at the practice is incompatible with e-prescribing products.
- 4.7% reported that there is a lack of e-prescribing products that meet the organizations' needs.
- 4.5% reported the lack of demand from customers (i.e., patients).
- 4.0% reported that it is too difficult to evaluate available e-prescribing options.
- 3.8% reported HIPAA compliance issues.
- 2.8% reported that it was because staff resists new technology.
- 2.6% reported that current e-prescribing products are not user-friendly.
- 2.4% reported there was a lack of buy-in at senior management level.

From the physician perspective, standards for e-prescribing must take into account the wide variety of clinical settings and specialties. We urge CMS to adopt final standards that are flexible and scalable to encourage adoption from small to large health care organizations and low-to high-volume prescribing physician specialties. E-prescribing standards must allow for basic stand alone e-prescribing platforms that permit small practices to meet the regulatory requirements without an undue financial burden. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency, and integration with existing management software and electronic medical record systems before making a further investment for e-prescribing. Physicians should also have the option of using a clearinghouse for e-prescribing, as they do with the standard transactions adopted under the Health Insurance Portability and

Accountability Act (HIPAA), until vendors can provide products that have been tested in the e-prescribing environment and that are interoperable with the physicians' practice management and electronic health record systems.

Standards for e-prescribing are currently deficient in the area of medical vocabulary, yet there does not appear to be a single solution to meet vocabulary needs. The AMA also believes that the terminology supporting patient data should be more comprehensive. For example, one of the suggested e-prescribing nomenclatures is RxNorm. RxNorm is a clinical drug nomenclature that provides standard names for clinical drugs and for dose forms as administered. It provides links from clinical drugs to their active ingredients, drug components, and some related brand names. To the extent available, National Drug Codes (NDCs) for specific drug products that deliver the clinical drug are stored as attributes of the clinical drug in RxNorm. However, the scope of the nomenclature needs to be broadened to account for other details such as packaging sizes, flavorings of oral medications, etc. The standard should more accurately capture "what the doctor ordered". RxNorm may need testing and enhancement before it will be suitable for use in the private sector.

In addition, interoperability with many clinical terms is also very important. For example, some terms may be used differently in a hospital setting than in a physician practice. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality, efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process.

The e-prescribing process should permit an entire electronic transaction seamlessly, from beginning to end. A physician should be able to efficiently submit a secure, authenticated prescription electronically in real time to a payer/pharmacy benefit manager for eligibility and formulary adjudication and the prescription should then be forwarded to the pharmacy. The physician must have the ability to communicate with the PBM, payer and pharmacy to provide further information on the patient if necessary, such as whether the patient has failed previous therapy, has a condition or allergy which makes the "preferred" drug an unacceptable alternative, etc. In addition, handwritten signatures should not be required, even for prescriptions of controlled substances. Whatever the scenario, the physician should never have to leave the e-prescribing environment to complete a prescription.

**Evolution and Implementation of an Electronic Prescription Drug Program**

The AMA recognizes the ambitious time frame mandated by MMA for CMS to implement the e-prescribing standards and the many standards that must be incorporated into an effective electronic prescription drug program. However, the AMA cautions against CMS adopting foundation standards without testing them in the e-prescribing environment.

Even though there may be adequate industry experience with a current standard in a particular environment, it is not certain how the use of the standard will work for e-prescribing. Although it is understandable that CMS would want to immediately adopt a few standards that have been independently tested, merely placing together standards in piecemeal fashion without testing them in the context of the "whole process" may lead to new problems that were not before seen or anticipated. CMS should not think in terms of standards that can be incrementally pieced together to make a "whole," but rather in terms of a whole system that is comprised of standards that work together and each add value to the whole. A "roadmap" of the complex e-prescribing environment should be developed first, and the component standards should then be identified, considered and tested.

Testing should include feedback on the level of acceptance from physicians and other prescribers in addition to feedback on usability, value and functionality. Without careful and deliberative standards development, there will not be widespread adoption and achievement of the promise of e-prescribing - improved efficiency, patient safety and health care quality. Pilot testing can also help determine appropriate financial models for funding the acquisition of technology, training and support for electronic prescribing in various clinical settings.

For these reasons, **the AMA believes that pilot projects should be conducted for all proposed e-prescribing standards in order to ensure that all of the standards will work seamlessly in multiple similar and dissimilar environments**. In addition, the pilot projects should address workflow issues and establish business rules in order to minimize potential burdens on physicians.

The AMA supports a true private sector approach to standards development for e-prescribing, with the federal government participating in the standards development process. However, we urge that the maintenance and modifications to the standards not get hindered by an extensive rule-making process similar to what has been experienced with the HIPAA administrative transactions standards. All vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and any interested party should be eligible to submit proposals for additions and modifications. In addition, a panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should be responsible for maintaining the vocabularies. Ultimately, the AMA agrees with CMS that any final standards should include only those standards that are accredited by the American National Standards Institute (ANSI). It may not be necessary for all the vocabulary developers to be ANSI accredited, however the organization maintaining the code sets should ensure continuity and efficient updating of the standard over time.

Finally, the AMA urges CMS to consider implementation of the e-prescribing standards in phases rather than requiring implementation of the entire set of standards by a single date. The implementation dates could be staggered by either function or by entity, or both.

**Electronic Prescription Drug Program and HIPAA Standards**

With respect to adoption of HIPAA standards, we suggest that CMS adopt minimal version levels of the standards, depend on existing standards development organizations processes for newer versions, and permit health care organizations to use newer versions provided there is backward compatibility. We agree with the Workgroup on Electronic Data Interchange (WEDI) that NCVHS should hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS should then recommend such changes to CMS. If NCVHS considers the change to be substantive, CMS should issue a proposed rule within 90 days. If the change is not substantive, it should waive a formal rulemaking and comment period.

Procedures should be designed to permit the changing needs of HIPAA and e-prescribing to be met but also ensure that such modifications to standards do not result in multiple standards. Again, the AMA recommends consideration of implementation in phases rather than requiring implementation of all standards by a single date.

With respect to privacy and security in general, the AMA believes that the e-prescribing final rule should apply the HIPAA Privacy and Security Rules to all systems for e-prescribing. However, the pilot testing should be designed to first identify any privacy issues that might arise in the event some part of the Privacy Rule may need modification in the e-prescribing context. As CMS mentions in the preamble, the "minimum necessary" rule in the HIPAA Privacy Rule will apply to any disclosures of protected health information in connection with an e-prescribing standard. Yet, if a disclosure is required for compliance with a HIPAA standard, the minimum necessary requirement may be waived. However, if the e-prescribing standard is not also a HIPAA standard, minimum necessary will apply. Although the AMA believes that the "minimum necessary" rule in the HIPAA Privacy Rule is an important privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for certain information, such as a listing of a patient's drugs, or his or her medical history, are likely to be highly complex. The AMA believes that a framework for the requisite controls must be thoroughly considered and tested prior to implementation of such standards.

**Standard Identifiers**

The AMA recommends that the HIPAA National Provider Identifier (NPI) be the primary identifier for prescribers and dispensers. However, the required date for use of NPI in transactions in this NPRM must not be accelerated before the required date for use of NPI in HIPAA transactions. There must be sufficient time after NPI capabilities for batch enumeration and data dissemination become available before the NPI can be mandated. The NPRM date of January 2006 is too soon because of non-availability of these NPI system capabilities. In addition, current identifiers should be used by prescribers and

dispensers until the NPI and its system, including batch enumeration and database access, are available.

**Formulary and Medication History Standards**

The AMA believes that the formulary, benefit and medication history messaging standards currently being developed should be thoroughly pilot tested before any standards become final. Vendors should be encouraged to bring products to market that assist physicians to comply with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide them with the tools necessary to comply with the electronic prescribing program.

We urge CMS to consider lessons the industry has learned from implementing the HIPAA Transactions and Code Sets rule. Implementation was severely delayed by the inability of the physicians and the provider community in general to upgrade their practice management and billing software in a timely manner. CMS had to resolve inter-governmental differences from across the Federal government in the Addendum to the Transactions and Code Sets rule. The additional time it took to resolve these differences left inadequate time for vendors to work with physicians and payers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long, and not conducive to industry usage.

The AMA is concerned that the criteria CMS outlines for medication history standards only technically states the objectives without a more detailed roadmap for implementation. These criteria are that the standards:

- are accredited by an ANSI-accredited standards development organization.
- permit interface with multiple product, router, and POC vendors.
- provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.
- provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.

These criteria will be very difficult to accomplish and there is potential for many practical complications that will require considerable time to implement.

As mentioned previously, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a

patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex. A framework for the requisite controls must be thoroughly considered and tested prior to implementation of the medication history standard.

The AMA is also concerned that the current industry models for retrieving prescription and medication history are developing and deficient thus far. Because patients often utilize multiple pharmacies, the prescription record at any one site is often incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

**Proposed Standards**

The AMA has a few concerns with the eligibility and benefits standard CMS proposes to adopt for inquiries between physicians and Part D sponsors. The ASC X12N 270/271 Eligibility Inquiry and Response Standard is inadequate. In the current HIPAA eligibility transaction a health plan can either give detailed benefit information or simply give a brief response: Yes-this person is eligible or No-this person is not eligible. Physicians need more detail than yes or no, and they need the information in a more consistent way.

Private industry groups, including health plans, physicians and other health care providers, are working together on a project to improve the quality of the eligibility responses to provide more information that is relevant and needed by physicians and other healthcare providers. The goal of the project is to encourage all health plans to respond to eligibility questions based on business rules established by the industry that are agreed to by health plans in concert with other key stakeholders, namely healthcare providers, vendors, and X12. This effort has just begun, but the goal is to finalize a first set of rules by December 2005. The AMA is a participant in this project and recommends that the requirement for better response information be strengthened in accordance with the findings of the outcome of the project.

The AMA believes that there should be further enhancement and testing of RxNorm as stated previously, and enhancement and testing of the National Drug File, Reference Terminology (NDF-RT) that is being developed for the Veterans Administration as a reference standard for medications to support a variety of clinical, administrative and analytical purposes. In addition, National Drug Codes (NDCs) work well for pharmacy purposes, but they are too granular for physicians to use for clinical purposes. As a result, many prescriptions today are transmitted in free-form text, resulting in re-entry and potential errors at the pharmacy, as well as lost opportunities for clinical decision support. The standards should support clinical decision making in addition to administrative tasks. Therefore, much work is still necessary in order to provide a consistent physician-level drug vocabulary.

Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

**Regulatory Impact**

To successfully implement voluntary electronic prescribing in the Medicare program, HHS should be fully aware of the future Medicare environment for physicians. By law, e-prescribing standards must be in place by April 1, 2009. At the same time, CMS actuaries predict five percent annual payment reductions for physicians for six years, starting in 2006. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. This means that by 2012, physicians will be paid about 26% less than in 2005, while practice costs will have increased significantly.

In this financial environment it will be extremely difficult for physicians to allocate the resources necessary to invest in new technologies. The AMA believes e-prescribing offers significant potential benefits to physicians and their patients. But investments in e-prescribing hardware and software may be difficult given the dramatic reimbursement reductions forecast in Medicare. The AMA urges CMS to eliminate the flawed physician payment formula, and to fund development of analysis and educational documentation making the financial and clinical case for e-prescribing investments by physicians.

Given the limited financial resources for many physician practices, the AMA appreciates that e-prescribing is currently voluntary. For widespread and successful adoption of e-prescribing in the near future, we underscore the need for an irrefutable, tangible benefit to patients and physicians. To this end, careful and deliberative standards development is critical to achieving the ultimate promise of e-prescribing - improved efficiency, patient safety and health care quality.

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In conclusion, the AMA would like to thank CMS for the opportunity to submit these comments. We look forward to additional CMS rules on the e-prescribing and pilot projects for 2006. If you have any questions regarding our comments, please do not hesitate to contact Anders Gilberg at (202) 789-4688.

Sincerely,

Michael D. Maves, MD, MBA

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Virginia L. Bartlett
Chief Privacy/Security Officer
U.S. Operations

IMS Health Incorporated
660 West Germantown Pike
Plymouth Meeting, PA 19462
Tel: 610-834-5635
Fax: 610-260-6640
Vbartlett@us.imshealth.com

April 5, 2005

Dr. Mark McClellan
Centers for Medicare and Medicaid Services
Attention: CMS-0011-P
PO Box 8014
Baltimore, MD 21244-8014

Dear Dr. McClellan,

IMS Health, the world's premier source of prescription intelligence, applauds the Centers for Medicare and Medicaid Services (and the advisory body, the National Committee on Vital and Health Statistics) for its work to advance the standard-setting process. As IMS Chief Privacy/Security Officer, I am pleased to offer comments on the Medicare Electronic Prescribing Proposed Rule (Fed Register Vol. 70, No. 23, Friday, February 4, 2005).

A demonstrated leader in precision statistical methodologies and accurate reporting for 50 years, IMS delivers a total picture of prescription activity across channels, locations, drug types and specialties. As a trusted partner to pharmaceutical and healthcare companies worldwide, we believe that patient information is among the most sensitive of all data and must be protected. More detailed information on IMS is attached.

In response to the CMS request for comments, IMS provides recommendations on four areas we believe will facilitate electronic prescribing. These specific suggestions are:

- Establish HIPAA Privacy as a foundation "standard";
- Develop a workable approach to preemption;
- Make inclusion of the National Provider Identifier optional until there is sufficient industry experience and a system for authentication and access; and
- Do no harm to statistical integrity during the uptake period.

IMS is available to provide assistance and further information on e-prescribing, health data privacy and standards development as needed. Thank you for your consideration of these comments.

Sincerely,

Virginia Bartlett
Chief Privacy/Security Office

## Overview of Comments on the Proposed Medicare Electronic Prescribing Rule

Passage of the Medicare Modernization Act (MMA) codified many key changes in the health care system, including an ambitious agenda for uptake of electronic prescribing within the Medicare program. Understood within the larger context of a National Health Information Network, we view electronic prescribing as a valuable tool for improving patient safety and cutting costs. IMS HEALTH (IMS) has engaged in policymaking on HIPAA, electronic prescribing and electronic health care, and work on the National Health Information Network by monitoring the National Committee on Vital and Health Statistics (NCVHS), meeting with key policymakers on Capitol Hill and within the Department of Health and Human Services, participating in relevant coalitions in Washington, and submitting official filings on related topics (including a response to the Office of the National Coordinator for Health Information Technology's Request for Information on the NHIN and interoperability).

IMS identifies the following components of an effective implementation of electronic prescribing and realized success of the agency's electronic prescribing objectives for patient safety and cost savings. For electronic prescribing to succeed, we believe electronic prescribing must:

1. Encourage prescriber adoption and meet state requirements for prescription drug dispensing;
2. Be interoperable with existing marketplace analytics to assure broadest acceptance of the standards;
3. Facilitate the tracking of drug utilization, therapy adherence and quality systems in order to improve patient safety;
4. Maintain patient confidence about safety, security, and value of the system; and
5. Further the goals of the National Health Information Network.

Our comments analyze electronic prescribing success within this framework.

## Patient Privacy: HIPAA Should Be A Foundation Standard

Our overarching view of both electronic prescribing and electronic health care is that attention must be paid to patient privacy, interoperability and the integrity of data systems and statistics that are key to advancing the President's goal of electronic health care, improvements in patient safety, and cost savings.

While IMS Health supports the standard setting underway as a means to motivate adoption of electronic health care, we believe acceptance may be more rapidly achieved by including as a foundation standard existing patient privacy and security protections. We believe HIPAA Privacy & Security Rules should be guiding principles for the implementation of electronic prescribing.

Recognizing and preserving the HIPAA Privacy Rule is essential to the success of e-prescribing. It is also an area that meets the adequate market experience baseline for a foundation standard as called out in the e-prescribing proposed rule. While the MMA does not require that physicians gain a patient's approval to electronically prescribe, we anticipate that as electronic prescribing, and electronic health generally, achieve market uptake, patient confidence – and willingness to participate – will be key to success. By adopting a known patient privacy standard at the outset of standard-setting, CMS may improve patient confidence in an electronic health system. A recent study found that Americans are divided on whether the benefits of electronic health care (patient safety, quality of care, etc) outweigh the risk (unauthorized disclosures of health information)[1]. Reinforcing the applicability of HIPAA as a foundation standard may help allay some of these concerns.

By applying HIPAA as a foundation standard to e-prescribing, the Department will also accomplish the baseline protections it will need to generate statistics and comparative value information from the dispensing activity that occurs inside an e-prescribing network. In particular, IMS highlights the section of the HIPAA Privacy Rule that contains the industry standard for the de-identification of patient data. Companies such as IMS already de-identify data successfully as standard practice. With HIPAA as a guide, the industry can create and release research statistics and link their own data to other types of health outcomes information. IMS believes this standard for de-identified data is an appropriate solution as CMS looks to analytics on dispensing activity, drug utilization, and therapeutic effectiveness as well as insight to therapy progression in treatment of specific diseases such as Parkinson's, analysis of concomitant medications and identification of those that might be contra-indicated in combination.

Acceptance of the HIPAA baseline is essential for anyone, including patient safety advocates, the FDA and medical researchers, who monitors prescribing activities and the drug pipeline for regulatory and other public good purposes. Prescriptions written in a new e-prescribing network may be for new patients or by physicians who have switched from paper prescriptions to electronic prescriptions. In either case, visibility is necessary to ensure valid public good results. By applying the HIPAA rules for access, CMS can capture this activity and assure statistical integrity during the uptake period.

The NCVHS aptly described the importance of privacy protections to the Secretary by stating, "the main privacy issue that needs to be resolved in an e-prescribing regulation is what rights consumers should have to limit access to their prescription records." While patient identifiable data is necessary for certain basic prescribing functions (ie: filling and claims processing), de-identifying patient data provides a means of using data for key research and patient safety and quality tracking while providing patients with the highest level of protection. We refer CMS to Dr. Alan Westin's

[1] Professor Alan Westin testifying at the National Committee of Vital and Health Statistics; February, 23, 2005.

(Professor of Public Law and Government at Columbia University) recommendation to the NCVHS that among other privacy considerations, a privacy working group should "identify and test anonymization techniques to enable both advanced medical research and data-analysis services."[2] Anonymization, or de-identification, promoted in HIPAA and the Privacy Rule for research and data analytics purposes, should be a model for data security in an electronic environment – especially at a time when security breaches and identity theft are at the forefront of public debate.

In summary, IMS urges that CMS establish the HIPAA Privacy and Security Rule as a baseline foundation standard for e-prescribing. Action taken now will facilitate confidence, establish certainty, and ensure patient acceptance of a known standard. It will also establish a means for CMS to maintain statistical integrity and evolve the value of e-prescribing.

**Preemption**

*"CMS invites comments on the scope of preemption."*

It is no surprise to see a continuation of debate on state preemption given either the intensity of negotiations during HIPAA deliberations or the much-debated use of "and" linking the two criteria for exemption of state law within the MMA.[3] If CMS chooses to stay with the current interpretation of preemption, we note the importance of investing in information solutions to help negotiate differences between federal and state law. The legal efforts involved with determining where state and federal laws intersect and diverge are extremely costly and time consuming and may well serve as yet another reason physicians cite for opting not to prescribe electronically. Thus, CMS should engage in discussions with industry on how best to bridge (using reference files) or "crosswalk" between information fields required to meet state and federal law. Doing so will diminish some of the legal and technological barriers to physician uptake.

Such crosswalks currently exist and are successful due to economies of scale (that is, large quantities of prescribing information that demand crosswalks between state and federal law enable a more cost-efficient means of creating and executing the crosswalks than if there were a fewer amount of prescriptions to consider). For example, IMS builds crosswalks between the federal and state Medicaid prescription drug rebate rules for pharmaceutical manufacturers. Without these information solutions, our clients would have enormous complexities involved with achieving a single rebate calculation in the

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[2] Dr. Westin's full testimony to the NCVHS is available at www.pandab.org and www.ncvhs.hhs.gov, see testimony from February 23, 2005. Dr. Westin expands on the recommendation: "From the start, EMR systems need to develop the identification filters and maskers that will enable researchers and data analysts to access anonymized health records sources. Surveys have shown the public to be very nervous about researcher access to their medical records, and this calls for powerful anonymizing processes to be installed, verified, and communicated to the public from the start, not retrofitted."

[3] Relevant section of the Medicare Modernization Act cited in the Proposed Rule on Electronic Prescribing: *Federal Register,* Vol. 70, No, 23: February 4, 2005. 6258.

context of state and federal laws. Our crosswalks are a cost-efficient way of achieving a single calculation. As a company that performs this service, we know that every change in regulations adds cost and confusion to meeting state and federal law. For example, under the new MMA, we will now need to account for the transition of dual eligibles from Medicaid to Medicare. That said, crosswalks that exist on a large scale (ie: broader than a single company or case) are a cost-efficient way of negotiating regulatory differences and changes.

To this end, IMS urges CMS to define crosswalks to state law and test such information solutions in pilot testing. We also encourage the Secretary to preempt state law for the purposes of pilot testing. Without doing so, pilot testing in certain states may be unable to occur or be ineffective.

**National Provider Identifier**

> *We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliances dates alternatives to the NPI, particularly in the short term and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process...NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispenser and the NCPDP HCIdea for identifying prescribers...We are looking at various options for an alternate identifier(s) , including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this as well..."*

IMS does not believe the NPI is an adequate prescriber identifier for electronic prescribing use at this point in time. We believe there are numerous unresolved short and long term problems with the identifier that need to be resolved before the industry can achieve the experience necessary for use.

In the short-term, the NPI will not be available widely in 2006, it has never been tested in industry in any capacity, and it fails to meet CMS' definition for a foundation standard for e-prescribing. Concerns that require further experience include: use of key information fields, crosswalks between the NPI and other industry identifiers, and failure to link the identifier to physical location or mandate that there be a single identifier per prescriber. Resolution of these issues is critical to the success of the NPI as an identifier and also to e-prescribing should CMS determine the NPI appropriate for use in the future.

The limited use of key information fields is inadequate. With only one location field[4] and a lack of validation during the enumeration process[5], there is very little means for users of the NPI to authenticate the NPI against other records and thus adequately protect against fraud and abuse – already a prescribing concern. While we understand that the Final Rule on the National Provider Identifier does give the Secretary of HHS the

[4] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3450

[5] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3446

authority to use the NPI for various purposes[6], we note for CMS that the decision not to validate physician-submitted information (in order to keep enumeration costs down) renders the NPI less valuable than other commonly used physician-identifiers. As another example, we would bring to CMS' attention that an NPI is not mandatory for all individual prescribers. If an individual does not require a unique NPI for billing, or is not a covered entity under HIPAA, then they need not apply for one.[7] This leaves a potentially disruptive gap for the processing of e-prescribing transactions and normal prescription claims processing, where an identifier is needed for all prescribers.

We urge CMS to thoughtfully consider the characteristics of the NPI that, while sufficient for claims processing, are not adequate for prescribing purposes. Such a consideration would look at the NPI's inability to ensure accuracy, credibility, and usability in a prescribing environment.

Therefore, it is our recommendation that in the short-term, CMS permit use of existing, currently used identifiers for electronic prescribing purposes. Other identifiers, including the SureScripts Prescriber ID (SPI), the DEA number, medical license numbers, and other proprietary identifiers are currently used widely in the industry for prescribing purposes and we recommend continued use until an identifier can be deemed sufficiently tested and workable for all industry partners. For example, after a period of use and when CMS resolves problems (such as validation and mandatory use for all individual prescribers) the NPI potentially could be an appropriate identifier.

In the event that the NPI is used in electronic prescribing, we urge CMS to ensure that the data dissemination strategy recognizes the importance of crosswalking between the NPI and legacy identifiers. Failure to do so will compromise the quality of health care data tracking, including the prescription drug monitoring that IMS does on behalf of both the government and the private sector. More importantly to CMS, if there are not accurate crosswalks available for all stakeholders in prescription claims processing, the new identifier will not be wholly adopted in that arena, and all the existing identifiers will continue to be used along with the NPI. Administration simplification therefore depends on creation and widespread availability of crosswalks. To this end, CMS should make the NPS reference files available so that data analysis may continue unhampered. This access must be permitted beyond HIPAA covered-entities. We recommend an approach that allows for file use to those who certify their compliance with relevant HIPAA regulations, including the Security Rule, in order to ensure appropriate use of the information.

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[6] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3449

[7] NPI Final Rule. Federal Register. Vol. 69, No 15. Friday, January 23, 2004. Rules and Regulations. P. 3438

Based on these concerns, IMS opposes adoption of the NPI as part of the e-prescribing rules until there the aforementioned concerns are appropriately addressed. In short, IMS urges the Secretary to in the final rule to:

1. Validate the continued use of authentication crosswalks such as the SureSpripts, DEA and Medical Education (issued by state license board) number at least until 2010;
2. Assert that within the e-prescribing network identifiers must be assigned for all individual prescribers; and
3. Mandate that physical location be tied to that prescriber.

Additionally, we do not view HCIdea as an adequate interim solution to the NPI. HCIdea is not currently widely used in the industry, does not meet CMS criteria for "adequate industry experience,"[8] and does not meet the criteria outline above.

**Other Comments: Interoperability Testing Is Needed for Metrics**

IMS believes the most efficient way to achieve the dual goals of e-prescribing and the NHIN is to facilitate, not replace, industry ability to generate metrics about prescription activity. Today, data that analyzes prescribing practices is key to many public health efforts, including tracking prescribing patterns, drug safety recalls, understanding drug utilization, treatment patterns and therapy progress, resource utilization, market trends and usage. In order to continue these essential functions, and, indeed, to facilitate the patient safety and quality tracking promise of electronic prescribing, CMS must ensure continued access to data. Continued access will prevent any inconsistencies or holds on the data flow to currently useful and thriving data tracking and analysis.

Two examples in which access to and use of de-identified data facilitate key public health functions while protecting patient privacy are:

1. In the marketplace today, the FDA requires that pharmaceutical manufacturers self-monitor and report new product market introductions to ensure appropriate prescribing and use. This is most frequently accomplished through use of statistics on dispensed prescriptions. Visibility to the data dispensed within an e-prescribing network is therefore essential to manufacturers compliance and patient safety.
2. Uses of prescription drug data by indication – where the patient is de-identified – can help to identify under-treated conditions, managed care management techniques and proper use of drugs for specific age groups, (e.g. antidepressants in children)

[8] Proposed Rule on Electronic Prescribing: *Federal Register,* Vol 70, No, 23: February 4, 2005. 6261.

These examples, each representing permissible activities under HIPAA, are also necessary for a successful e-prescribing network, EMR and NHIN. Given the critical importance of this issue, IMS strongly recommends that statistical interoperability be tested in the pilot projects and that there be two goals: 1) to assure integrity; 2) to develop a comparative base about in-network dispensing for the marketplace. Specific issues such as the impact of additional and conflicting points of collection can also be included in test requirements.

**Conclusion**

IMS appreciates the opportunity to offer these comments on this important initiative and hopes CMS will:

- Protect patient privacy and research by recognizing the HIPAA Privacy and Security Rules as a foundation standard.
- Allow for continued access to and use of de-identified patient data as set forth in the Privacy Rule;
- Explore the role information solutions can play in helping stakeholders meet requirements of state and federal laws, should the narrow interpretation of preemption remain;
- Consider the characteristics of the NPI that make it an insufficient identifier for prescribing purposes and recommend continued use of multiple identifiers for prescribing use; and
- Include statistical interoperability as a component of pilot testing to ensure ongoing data integrity.

We look forward to the next phase of electronic prescribing rulemaking and engaging in forthcoming pilot projects.

**Attachment:**
**Background on IMS Health**

IMS HEALTH is the world's leading provider of information, research, and analysis to the pharmaceutical and health care industry with data collection activities in over 100 countries. In the United States alone, the company collects information from pharmaceutical wholesalers, pharmacies, physicians, hospitals, and clinics, and processes over 375 million de-identified records each month.

IMS HEALTH's business includes tracking patterns of diseases, treatments, outcomes, prescriptions, and sales of pharmaceutical products. The company receives and analyzes de-identified data. Using this data, we are able to assist the medical, scientific, and health care management communities in conducting outcomes research, implementing best practices, and applying health economic analyses. The company's databases of de-identified prescription drug transactions are essential to effective implementation of prescription drug recall programs, performance of pharmaceutical market studies, and assessment of drug utilization patterns (i.e., on- and off-label uses and regional variations in prescribing behavior).

IMS HEALTH recognizes the sensitivity of health information and has operated with long-standing comprehensive practices to protect the privacy of individuals and preserve the confidentiality of the information we collect. These practices include: requiring that transaction data be de-identified prior to being sent to IMS HEALTH; screening records before acceptance to ensure that they are de-identified; tightly controlling access to data; requiring informed patient consent before collecting any individually identifiable information; restricting use of information; routinely auditing information practices; and entering into confidentiality agreements with data sources, employees, and clients.

#19 9/

MGMA

MGMA Center for Research
American College of Medical Practice Executives
Medical Group Management Association

April 5, 2005

Mark McClellan, M.D., Ph.D.
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-0011-P
P.O. Box 8014,
Baltimore, MD 21244-8014

**Re: Medicare Program; E-Prescribing and the Prescription Drug Program; Proposed Rule**

Dear Administrator McClellan:

The Medical Group Management Association (MGMA) appreciates the opportunity to comment on the proposed rule on e-prescribing. MGMA is the nation's principal voice for medical group practice. MGMA's 19,500 members manage and lead more than 11,500 organizations in which more than 240,000 physicians practice. Our individual members, who include practice managers, clinic administrators and physician executives, work on a daily basis to ensure that the financial and administrative mechanisms within group practices operate efficiently so physician time and resources can be focused on patient care.

**General Comments**

As the federal government and the health care industry move toward adoption of standards for electronic prescribing, the following issues should be considered:

- E-prescribing Standards Should be Flexible and Scalable – From the physician perspective, standards for electronic prescribing must take into account the wide variety of clinical settings and specialties. The final standards must be both flexible and scalable to encourage adoption by both small and large health care organizations and low- to high-volume prescribing physician specialties. The standards should also provide for the needs of larger, more complex group practices and health systems. This flexibility will allow physicians to consider critical factors such as clinical quality, safety, efficiency and integration with existing practice management software and electronic medical record systems when making an investment.

- E-prescribing Standards Should not Impose Undue Burdens on Providers – In these challenging economic times, with decreasing reimbursement and increasing practice expenses, it is critical that the Centers for Medicare and Medicaid Services (CMS) craft a final rule that does impose undue financial burdens on physician practices. Furthermore, e-prescribing systems should be designed in such a way that clinicians are able to utilize this technology in a time-efficient manner. Clinicians may be discouraged from adopting the technology if it takes them significantly more time to write a prescription electronically than on paper.

HEADQUARTERS
104 Inverness Terrace East
Englewood, CO 80112-5306
phone: 303.799.1111
fax: 303.643.4439

GOVERNMENT AFFAIRS
1717 Pennsylvania Avenue
North West, Suite 600
Washington, DC 20006
phone: 202.293.3450
fax: 202.293.2787

www.mgma.com

- Ensure System Interoperability – In order for an electronic prescribing system in a medical practice to communicate effectively and securely and share patient data with other medical practices, hospitals and pharmacies, they all must speak the same "language." E-health standards developed by either the federal government or industry must have the ability to be utilized by multiple stakeholders using a myriad of computer systems. At the same time, "interoperability" should also include the ability for an electronic prescribing system to seamlessly interact with other clinical and administrative systems in the practice.

- Promote the Security and Privacy of Patient Data – Patients are more concerned than ever about maintaining the security and privacy of their health information. At the same time, providers are embracing the new standards in these areas as mandated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). E-prescribing must maintain these HIPAA standards as part of its core operating features.

- Establish a Quantifiable Return on Investment – For many group practices, the economics of investing in e-prescribing and other health information technology is simply not evident. In an environment of significant scheduled Medicare reimbursement cuts, sharply rising malpractice premiums and ever-increasing practice expenses, many practices are concerned that moving to an electronic information system will not be financially beneficial. MGMA recommends that CMS establish a quantifiable return on investment through survey research and a comprehensive cost/benefit analysis for all sizes of physician practices.

- Incentives for Providers – While medical practices typically absorb the cost of purchasing the health information technology necessary for electronic prescribing many of the benefits accrue to others in the system. MGMA believes there should be a "realigning" of these incentives by promoting appropriate public and commercial reimbursement programs. MGMA has supported the concept of a federal program of tax credits for physician investments in health technology that could serve as a significant incentive. Additionally, a federally guaranteed loan fund for physician health technology investments, coupled with loan forgiveness for service to medically underserved populations, could also be a stimulus.

- Technology Savings Accounts – The federal government should also explore innovative methods of assisting physician practices to acquire health information technology such as electronic prescribing. Technology Savings Accounts (TSAs) would provide a reduced level of taxation for funds designated for practice health information technology. A TSA would be a special account owned by a group practice where contributions to the account pay for current and future qualified health information technology expenses including electronic prescribing software and hardware. A TSA savings product offers a different way for group practices to pay for their health information technology expenses. TSAs could enable group practices to pay for current expenses and save for future qualified health information technology expenses on a tax-free basis. Unspent account balances would accumulate and accrue interest.

- Stark Regulation Safe Harbor – There are clear legal barriers to the adoption of health technology solutions in medical groups. Anti-kickback and self-referral concerns prevent some health care organizations from offering free or discounted technology to medical practices. MGMA has advocated for government approval of legal protections, such as safe harbors and regulatory exceptions, to facilitate health technology implementation. We congratulate the CMS recent important step in this direction through its creation of a health technology safe harbor in the physician self-referral phase II interim final rule (CMS-1810-IFC; 59 Fed Reg 16054).

- Consultation with the Physician Practice Community – Physician practices must play an integral role the development and deployment of any standardized e-prescribing system. Since the vast majority of all health care is delivered in medical practices, the success or failure of these initiatives will depend heavily upon physician acceptance of this new technology. MGMA encourages CMS to continue its outreach to this community to ensure that the requirements and concerns of physicians are addressed.

- Patient and Provider Outreach – The successful adoption of e-prescribing will depend, in part, on the ability of the federal government and the industry to encourage both providers and pharmacies to understand and support the system. It is imperative that these two critical stakeholders are well educated as to the systems' capabilities as well as its security and privacy components. In addition, MGMA recommends that CMS work with the appropriate provider and consumer associations as well as the popular media to deliver a consistent message to patients on this important change in the health care system.

- Work with the industry to expand this regulation beyond Medicare Part D – This regulation is expected to enhance patient safety and efficiency for the Medicare Part D program. CMS should expand the use of this standard beyond Medicare and MGMA is hopeful that a successful implementation of this regulation will trigger adoption of these standards by the private sector. MGMA encourages CMS to facilitate this expansion by working with the private sector to exchange data and experiences as well as develop educational materials that will assist stakeholders move forward with e-prescribing.

- Learn from the HIPAA Experience – The protracted nature of HIPAA Transactions and Code Sets implementation process suggests that the federal government's e-health regulatory process must be modified. MGMA calls on the government to stagger implementation dates, thus providing health plans and clearinghouses time to upgrade and test systems before provider implementation takes effect. While piloting is not needed to establish the applicability of the core function standards, piloting of the entire e-prescribing standard should be completed prior to full national implementation in order to identify and correct problems.

**Specific Comments on the Notice of Proposed Rule Making**

Issue: **State Preemption (70 Federal Register No. 23 Feb. 4, 2005 page 6258)**

*We invite public comment on our proposed interpretation of the scope of preemption, particularly with respect to relevant State statutes and regulations which commenters believe should be preempted, but would not under our proposed interpretation. We specifically ask for comment on whether this preemption provision applies only to transactions and entities that are part of an electronic prescription drug program under Part D or to a broader set of transactions and entities. We also ask for comment on whether this preemption provision applies to only electronic prescription transactions or to paper transactions as well.*

Response:

MGMA believes that the proposed rule adopts a very narrow interpretation of federal preemption. The rule appears to limit preemption to only those Part D beneficiaries enrolled at the time the prescription is issued, rather than all Medicare beneficiaries. We also have a concern that Medicare beneficiaries may receive drug coverage from multiple sources. Yet, the rule seems to limit preemption to only those prescriptions actually covered by Part D. MGMA recommends that CMS adopt an interpretation providing that federal law broadly preempts any state laws that are contrary to

or that stand as an obstacle to the objectives of the federal government in creating the e-prescribing standards. We believe that this interpretation is consistent with the settled view of preemption and statutory language. MGMA also suggests to CMS that the preemption standard apply to any prescription issued to any beneficiary eligible for Part D coverage.

Issue: **Current E-prescribing Environment (70 Fed Reg 6260)**

*The use of e-prescribing shows promise for improving Medicare operations by creating efficiencies in the administration of the Part D drug benefit, by decreasing costs in facilitating patient eligibility checks, promoting generic drug use, and creating timely interface with formularies. This also allows enhanced patient safety benefits through the prevention of medication errors resulting from illegible handwriting on paper prescriptions.*

Response:

MGMA believes that e-prescribing will help to deliver relevant patient information and clinical knowledge to the clinician and this will reduce the likelihood of a faulty prescription. In addition, e-prescribing holds the promise of improved administrative efficiencies. Presenting all relevant information to the clinician at the time of prescribing may help streamline the entire prescribing process. Relying solely on downstream inspection to manage quality is inefficient because of the extra work required. By some accounts, the nation's three billion prescriptions generate approximately 150 million clarification phone calls every year. This means that roughly five percent of prescriptions are somehow incompletely specified or unclear, and need to be reworked.

Early experience supports the view that electronic prescribing – by shifting the error-inspection process to the point of prescribing – reduces callback volume and improves efficiency. In fact, most clinics that successfully deploy electronic prescribing applications note a dramatic decrease in prescription clarification calls. Moreover, those callbacks that still occur can usually be processed more efficiently because of the streamlined message-handling capabilities that often come with electronic prescribing, coupled with elimination of the need to pull (and re-file) paper charts every time a pharmacist or patient calls with a question or concern about a prescription. This reduction in chart pulls is one of the unheralded beneficial side effects of electronic prescribing and has major cost-savings implications, particularly for larger practices. Even in small practices, however, there is still significant time lost looking for charts that have not been filed and are in multiple locations around the office, waiting for various processes to be completed.

Issue: **Evolution of Standards (70 Fed Reg 6261)**

*We invite public comment on how to establish a process that will be used to evolve currently adopted and additional standards and to determine an appropriate implementation sequence, consistent with the Administrative Procedures Act and other applicable legal requirements. We specifically invite comment regarding the role of industry standard setting organizations and the NCVHS.*

Response:

MGMA supports the creation of e-prescribing standards as needed by the private sector through ANSI accredited standards developing organizations, with federal government participation in the standards development process. We urge that the maintenance and modifications to the standards not be hindered by an extensive rule-making process similar to that experienced with the HIPAA Transactions and Code Set standards. In addition, MGMA recommends that all vocabulary and coding systems referenced for use in the e-prescribing standards should have an open updating process and

any interested party should be eligible to submit proposals for additions and modifications. A responsible panel or committee of experts that are representative of a broad cross-section of the relevant stakeholders should maintain these vocabularies.

Issue: **Criteria to Assess "Adequate Industry Experience" (70 Fed Reg 6261)**

*We propose to use the following criteria to assess adequate industry experience (with transaction standards), based on testimony presented to the NCVHS and on some of the NCVHS discussions, and we solicit comments on these criteria:*

- *The standard is American National Standards Institute (ANSI) accredited. We propose this criterion because the ANSI accreditation process is open and based upon consensus, so accredited standards are more likely to adequately address, and effectively respond to, industry needs.*

- *The standard generally has been implemented by entities to which the final standard will be applied in multiple e-prescribing programs with more than one external health care partner. We propose this criterion because it demonstrates that the standard can be successfully implemented, the experience can be replicated, and the standard is interoperable between organizations as well as within an organization.*

- *The standard is recognized by key industry stakeholders as the industry standard. We propose this criterion so that we do not adopt a standard in a situation where there are competing industry standards and the industry is divided over which one should be selected.*

Response:

MGMA agrees with this approach to determine if a standard is deemed to have had "adequate industry experience." We would like to emphasize the importance of the final bullet, that the standard be recognized by key industry stakeholders, as this is critical to ensure that the standard has been used in clinical settings and found to be acceptable. In particular, we encourage CMS to continue its outreach to the provider community to ensure that any futures, standards take into account the requirement of clinicians.

Issue: **Drug orders for fill status notification (70 Fed Reg 6262)**

*NCVHS Standards Recommendations – HHS Should :include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. Standard in the NPRM: No.*

Response:

MGMA is disappointed that CMS decided not to include the fill status notification function of the NCPDP SCRIPT standard in the 2006 pilot tests. This standard has the potential of significantly improving the health of Medicare beneficiaries. With some industry sources estimating that up to 40 percent of written prescriptions are never filled by the patient, it is clear that many patient conditions are not easily monitored by physicians.

Failure to refill medications at a pharmacy or renew at the clinician's office in a timely fashion can and does lead to adverse events due to exacerbations of the condition. This is a significant problem particularly for persons who have difficulty affording their prescriptions. Renewing prescriptions in a timely fashion may not be a high priority, especially for drugs that treat relatively asymptomatic

chronic conditions. Lack of patient compliance with prescribed medications can also lead to similar adverse events. With electronic prescribing systems leading to better tracking of a patient's drug regimen, it is possible to know when renewals of regularly scheduled medications are likely to come due, assuming proper patient compliance. Systems can send out reminders to patients and clinicians, advising of an upcoming renewal or refill time and even offering one-click renewal transactions. These reminders should have a positive impact on actual compliance.

It would be easy for elderly Medicare beneficiaries, who may be taking multiple prescription drugs, to miss filling an important prescription. Thus, prescription fill status could be an important device allowing clinicians to better monitor chronic care illness, potentially lowering overall health costs by preventing hospitalizations due to improper drug usage. In addition, fill status would potentially be an important patient safety, patient satisfaction and quality measurement. We are hopeful CMS will consider including this function in later standards.

Issue: **Version Control (70 Fed Reg 6267)**

*If standards are updated and newer versions are developed, HHS would evaluate the changes and consider the necessity of requiring the adoption of new updates to the standards. This would be done through the incorporation by reference update approval process, which provides for publication in the Federal Register of an amendment to a standard in the Code of Federal Regulations. If the updates include substantive changes such as new functions that we consider necessary to be implemented for an e-prescribing transaction, we would modify the required standards through subsequent notice and comment rulemaking. If, on the other hand, the updates or newer versions simply correct technical errors, eliminate technical inconsistencies, or add functions unnecessary for the specified e-prescribing transaction, the Secretary would consider waiving notice and comment. In the later case, we would likely adopt the version that was previously adopted as well as the new version. This means that compliance with either version would constitute compliance with the standard.*

Response:

MGMA recommends that HHS (i) adopt minimal version levels of the standards; (ii) depend on existing standards developing organization (SDO) enhancement processes for newer versions; and (iii) permits health care organizations to use newer versions provided there is backward compatibility. MGMA recommends that the National Committee on Vital Health Statistics (NCVHS) hold hearings, scheduled annually or semiannually, to determine when new minimum version levels should be adopted. NCVHS would recommend such updates to HHS. If NCVHS considers the change to be substantive, as described on 70 Fed Reg 6267 above, HHS would issue a NPRM within 90 days. If the change is deemed not to be substantive, it would waive notice and comment.

MGMA is concerned about any possible divergence between a HIPAA standard transactions and the same e-prescribing transaction, such as the ASC X12N 270/271 eligibility inquiry. MGMA recommends that procedures be designed to permit the changing needs of HIPAA and e-prescribing to be met but that such modifications to standards do not result in multiple standards. MGMA also recommends consideration of implementation phases rather than requiring all transactions by a single date.

Issue: **National Provider Identifier (70 Fed Reg 6263)**

*We invite public comments on the possible use of the NPI for Medicare Part D e-prescribing transactions; the earliest time when the NPI should be required for use in an electronic prescription drug program; the effect on industry of accelerating use of NPI in an electronic prescription drug program ahead of the HIPAA compliance dates; alternatives to the NPI, particularly in the short term; and options for phasing in use of the NPI in e-prescribing transactions or prioritizing budget concerns that could delay the enumeration process.*

*NCVHS recommended that HHS permit the use of the NCPDP Provider Identifier Number for identifying dispensers and the NCPDP HCIdea® for identifying prescribers in the event that the National Provider System (NPS) cannot enumerate these providers in time for Medicare Part D electronic prescription drug program implementation. We are looking at various options for an alternate identifier(s), including using provider identifiers currently in use in the Medicare program, in the event the NPI is not available for use, and we invite public comment on this, as well.*

Response:

MGMA is a strong supporter of administrative simplification and believes that the national provider identifier (NPI) is an important step in streamlining health care transactions. The NPI should be the primary identifier for all prescribers and dispensers utilizing e-prescribing. MGMA recommends that current identifiers not be required to be used by prescribers and dispensers until NPI and its system, including batch enumeration and database access are available.

In addition, while MGMA recommends that the required date for use of the NPI in transactions in this NPRM not be sooner than the required date for use of the NPI in HIPAA transactions, we strongly urge CMS to move forward with the NPI enumeration process. E-prescribing will be greatly facilitated with a standard provider identifier. We recommend that CMS work with providers and other stakeholders to develop an NPI implementation plan that results in rapid and successful adoption of this important new standard.

Issue: **Formulary and Medications Standards (70 Fed Reg 6263)**

*We set out the characteristics we consider to be critical for formulary, benefit, and medication history messaging at the end of this section, and solicit comments on those characteristics. We further solicit comment on the extent to which any candidate standards, including the RxHub protocols, meet those characteristics and should be considered for adoption as foundation standards. We propose the following critical characteristics for formulary and benefit data standards:*

Response:

In order to facilitate a successful implementation, MGMA recommends that the formulary, benefit and medication history messaging standards should be thoroughly pilot-tested prior to the release of a final rule. Vendors should be factored into the regulations and encouraged to bring products to market that assist physicians in complying with the statutory requirements ahead of any deadlines. Staggered implementation dates should be considered, as pharmacies and pharmacy benefit managers must have systems up and running to allow physicians to send test prescriptions that comply with new standards. Physicians must rely on their vendors to provide the tools necessary to comply with the electronic prescribing program. Strong government leadership will be critical to rapid and seamless conversion to the new standard.

MGMA urges that HHS make final recommendations in the context of lessons learned from implementing the Administrative Simplification provisions of HIPAA. A critical factor in the protracted implementation of the Electronic Transactions and Code Sets rule has been the inability of the provider community to upgrade their practice management and billing software in a timely manner. HHS had the most difficult task of trying to resolve inter-agency differences from across the federal government in the Addendum to the Electronic Transactions and Code Sets rule (citation). The additional time to resolve these differences left inadequate time for the various vendors to work with their provider and payer customers to achieve timely compliance with the new rule. Further, the governmental process for naming a new version or a new standard under HIPAA is too cumbersome, too long and not conducive to industry usage.

Issue: **Medication History (70 Fed Reg 6263)**

*We propose the following critical characteristics for medication history standards:*

- *The standards are accredited by an ANSI-accredited standards development organization.*
- *The standards permit interface with multiple product, router, and POC vendors.*
- *The standards provide a uniform means for a prescriber, dispenser, or payer to request from a payer, dispenser, or prescriber, a listing of drugs that have been prescribed or claimed for a patient within a certain timeframe.*
- *The standards provide a uniform means for a Part D plan, dispenser, or prescriber to request from a prescriber, dispenser, or Part D plan, information to describe the patient's medication history. This includes, for example, the drugs that were dispensed within a certain timeframe, and may include the pharmacy that filled the prescription and the physician that wrote the prescription.*

Response:

MGMA recommends private sector development and maintenance of standards and modifications and enhancements to standards not be hindered by extensive rule-making processes. We are concerned that these criteria outline only a technical view of the objectives. They describe a very difficult goal with many practical complications requiring considerable time to implement. Although theoretically the "minimum necessary" clause in the HIPAA Privacy rule is powerful privacy protection, the controls necessary to know what is minimally necessary and to prevent more than the minimum necessary in responses to requests for a listing of a patient's drugs, or his or her medical history in a certain timeframe, are likely to be highly complex.

MGMA is also concerned that the current models for retrieving prescription and medical history is daunting. For example, patients often utilize multiple pharmacies—often making the prescription record at any one site incomplete. The diagnostic reason for a prescription is often inaccurate. Frequently, a prescription is written, not as therapy for a known diagnosis, but to rule out a diagnosis, and a record of the outcome is not recorded.

Issue: **Proposed Standards (70 Fed Reg 6264)**

*We invite public comment on these proposed standards, as well as on standards currently being used in the industry that meet the proposed functionalities for formulary and medication history and could serve as foundation standards. In addition, we invite public comment on the feasibility of, and alternatives to, the*

*strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA-organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking. Pilot testing will be required unless the exception for adequate industry experience applies (followed by rulemaking to adopt the final standards.) In addition to the standards regarding formulary and medication history if certain characteristics are met, we are proposing to adopt, as foundation standards, the following:*

- *The NCPDP SCRIPT Standard Version 5, Release 0 (Version 5.0), May 12, 2004 (hereafter referred to as the NCPDP SCRIPT Standard).*

- *The ASC X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 4010, May 2000, Washington Publishing Company, 004010X092 and Addenda to Health Care Eligibility Benefit Inquiry and Response, Version 4010, October 2002, Washington Publishing Company, 004010X092A1 (hereafter referred to as the ASC X12N 270/271 Transaction).*

- *The NCPDP Telecommunication Standard Guide, Version 5, Release 1 (Version 5.1), September 1999, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 1 (Version 1.1), January 2000 supporting Telecommunications Standard Implementation Guide, Version 5, Release 1 (Version 5.1) for the NCPDP Data Record in the Detail Data Record (hereafter referred to the NCPDP Telecommunication Standard).*

Response:

MGMA agrees with moving forward with these "foundation" standards. It is clear that the industry has already adopted these standards and that they meet the basic needs of the industry. However, MGMA encourages moving to new standard versions as soon as practical, in particular, moving to the new versions of the ASC X12N 270/271 and 278. MGMA also agrees that these foundation standards do not need to be piloted to determine their applicability to the e-prescribing regulation. However, as noted above, we encourage CMS to initiate a comprehensive pilot of the entire standard prior to implementation.

For future additions to the standard, MGMA recommends pilot projects in order to prove the standards not named as foundation standards will work in multiple provider and pharmacy environments. As well, pilot projects should address workflow issues and establish the business rules in order not to impose undue burden on physicians and pharmacies. MGMA recommends that demonstration pilots show achievable financial models for appropriately funding the acquisition of technology, training and support for electronic prescribing in various clinical settings. Pilot projects may also be required for any standard already demonstrated but being proposed for use in new circumstances.

Issue: **Strategy for Phasing in Implementation of an Electronic Prescription Drug Program (70 Fed Reg 6264)**

*In addition, we invite public comment on the feasibility of, and alternatives to, the strategy we are proposing of phasing-in implementation of an electronic prescription drug program by requiring providers, dispensers, MA organizations, and PDPs engaged in e-prescribing to comply initially (beginning January 2006) with the*

*following proposed standards by requiring, at a future date, compliance with other necessary standards as they are adopted in subsequent rulemaking.*

Response:

MGMA agrees with this phased in approach to the e-prescribing standards. It is important to have the foundation standards adopted quickly by the industry to ensure that the benefits of e-prescribing are achieved in a timely manner. It is also important to move forward with the additional standards with all deliberate speed, with the caveat that these standards be properly vetted through the appropriate standards organizations and piloted when there is insufficient industry experience. MGMA encourages CMS to institute a comprehensive industry outreach program, focused on the provider community. Each release of a new e-prescribing standard should be prefaced with an educational program to explain the new standard and how it should best be implemented.

Issue: **Eligibility (70 Fed Reg 6266)**

*We are proposing, at new §423.160(b)(2)(i), to adopt the ASC X12N 270/271 Transaction, for conducting eligibility and benefits inquiries between prescribers and Part D sponsors...*

*Currently, there are efforts by the NCPDP to create a guidance document that will map information on the Medicare Part D Pharmacy ID Card Standard to the appropriate fields on the ASC X12N 270/271 transaction. However, it is important to note that the level of detail returned on the 271 by the Part D sponsor must match the level of detail in the inquiry made by the prescriber in the 270 request, to the extent that the Part D sponsor's system is capable of handling this request.*

*We are proposing to adopt, at proposed §423.160(b)(2)(ii), the NCPDP Telecommunication Standard, for conducting eligibility transactions between dispensers and Part D sponsors. First, these standards adhere to EDI for EDIFACT and ASC standards.*

Response:

For eligibility inquiry and response, MGMA supports the ASC X12N 270/271 for the patient eligibility and benefits inquiry. The eligibility transactions for prescribers and Part D sponsors should match the appropriate ASC X12N 270/271 transactions named in HIPAA. However, as much as this transaction has the capability of significant return on investment by reducing the cost for both medical practices and health plans to verify patient eligibility, in reality, much of the value of this transaction has not been realized. Medical practices report that health plans are simply responding with a "yes" or "no" when queried. While this is permitted under HIPAA, this minimum level of response necessitates the practice use the telephone to ascertain other eligibility information from the health plan – thus incurring significant costs to their organization and for the health plan.

We are hopeful that a recent industry initiative may assist in providing additional electronic eligibility and benefits information to medical practices. MGMA is working with Council for Affordable Quality Healthcare (CAQH) to improve the quality of 271 eligibility responses from health plans in order to provide more information that is relevant and needed by physicians and other healthcare providers. The CAQH is seeking to define operating rules that health plans will voluntarily adopt, providing information as to whether the patient is covered and guidelines for benefit information. This information may provide pointers to the formulary and benefit information the prescriber system has received, which may provide additional information. MGMA recommends that CMS consider modifying the 270/271 to include these operating rules as required data elements in future versions of

the standard.

Issue: **Coordinate Update Process when e-prescribing and HIPAA Standards are the Same (70 Fed Reg 6267)**

*We note that, if an e-prescribing transaction standard has also been adopted under 45 CFR Parts 16 through 162, we would coordinate the updating process for the e-prescribing transaction standard with the maintenance and modification of the applicable HIPAA transaction standard. We also seek comment on whether we should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.*

Response:

MGMA recommends that CMS not approach standards that fall within the purview of both e-prescribing and HIPAA differently. CMS should simply reference the relevant HIPAA standard so that this standard will be updated automatically in concert with any HIPAA standard modification.

Issue: **Regulatory Impact Analysis (70 Fed Reg 6268)**

*We invite public comment on our expectations for prescriber participation.*

Response:

To implement voluntary electronic prescribing in the Medicare program successfully, HHS must be fully aware of the future Medicare environment. By law, electronic prescribing must be in place by April 1, 2009. At the same time, CMS actuaries predict approximately five percent reductions each year in Medicare reimbursements to physicians from 2006-2011. Concurrent with these cuts, the costs to care for patients are likely to continue growing at a pace that exceeds inflation. The result is that by 2014, after eight years of reductions, physicians will be paid about 40 percent less than in 2005, while practice costs will have increased significantly. Finally, although matching grants have been authorized to help the adoption of electronic prescribing, funds have not yet been appropriated.

In this financial environment, it will be extremely difficult for physicians to allocate the resources necessary to invest in new technology unless it provides an irrefutable, tangible benefit to their patients and practice. To this end, careful and deliberative standards development is critical to widespread adoption and achievement of e-prescribing's promise of improved efficiency, patient safety and health care quality. MGMA believes that e-prescribing offers significant financial and other benefit potential to providers. However, this observation may not appear compelling to many providers in the financial environment between now and 2011. MGMA recommends that CMS fund the development, analysis and educational documentation making the financial case for providers to implement health information technology.

Issue: **Standards Development Approach (70 Fed Reg 6264)**

*While one option might be to postpone the establishment and adoption of standards for e-prescribing until such time as there are commonly accepted industry standards for EHRs, so that standards for the interoperability of e-prescribing and EHR systems could be established at the same time, this would postpone the implementation of any e-prescribing functionality, including the attendant benefits and is beyond the scope of the MMA. We are proposing foundation standards that*

*are ANSI accredited and have adequate industry experience, which we believe will facilitate interoperability with later industry-adopted standards for EHRs as well as interoperability across software and hardware products. In addition, consideration will be given to future requirements for interoperability. We solicit comment on this approach, as well as on other critical success factors for assuring interoperability.*

Response:

MGMA believes interoperability with many clinical terms is very important. For example, some terms may be used differently in a hospital setting than an ambulatory environment. Final standards may need to be enhanced where necessary, as well as support vocabularies that clearly define the intent of the prescription. Improved vocabularies and standards are needed to enhance quality and efficiency, and to facilitate interoperability between the various electronic systems involved in the e-prescribing process. Prescribing system drug dictionaries also need to be consistent so that specifications of allergy groups, drug interaction groups, etc. are interoperable between different applications that use different commercial dictionaries. Once agreement has been reached on a vocabulary, it should be incorporated into the definitions and requirements of the NCPDP SCRIPT standard.

Issue: **Regulatory Impact (70 Fed Reg 6269)**

*We are soliciting public comment on the estimates used to determine the regulatory impact for this proposed rule. Because of the current lack of adequate data, we are unable to completely quantify the full costs and savings that may be achieved in implementing electronic prescription drug programs under the MMA. We are asking for public comment and input on the data and issues presented in this impact analysis.*

**Provider Savings, especially solo and small groups (70 Fed Reg 6270)**

*We request public comments and additional information on actual and potential savings, particularly in solo and small group practices.*

**Applying the ROI of larger practices to smaller practices (70 Fed Reg 6270)**

*These examples come from large practices, but we would expect that most if not all of them would apply equally well to smaller practices. We request public comments and additional information on actual or potential savings, particularly in solo and small group practices.*

Response:

Without conducting a wide-ranging survey, MGMA is not in position to provide a detailed impact analysis of these proposed regulations on different types of participants. It is critical, however, that CMS develop a comprehensive and accurate report of the full costs and savings in order to fully understand the impact that this regulation will have on the industry. In particular, MGMA encourages CMS to conduct this important analysis as soon as possible as the results will not only help to guide the policy development process but may also help to facilitate the provider community's acceptance of this technology. It appears as though only a small percentage of practices are currently utilizing e-prescribing, though a significant number are expecting to move to this technology over the next 24 months. MGMA, however, is positioned and willing to develop and analyze surveys for CMS, as well as educational documentation, analysis and financial models, and pilot and testing projects.