**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

CMS-0011-P-22-Attach-1.PDF

**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

**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.

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**Submitter :** **Mr. Steve Tucker** **Date: 04/05/2005**

**Organization :** **PacifiCare Heatlh Systems**

**Category :** **Health Plan or Association**

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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

**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.

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.

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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)

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? 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

**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