Submitter : Mrs. Wendy Schrag **Date:** 12/18/2006

Organization : Fresenius Medical Care North America

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-100-Attach-1.DOC

Fresenius Medical Care

December 18, 2006

Ms. Leslie Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4119-P
P.O. Box 8017
Baltimore, MD 21244-8017

RE: Public Comments, CMS-4119-P

Dear Ms. Norwalk:

Thank you for the opportunity to provide public comment on the proposed rule to allow the Secretary to use Part D claims information for research, analysis, reporting, and public health functions. These comments are being submitted on behalf of Fresenius Medical Care North America (FMCNA), the largest supplier of dialysis supplies and services in the United States. We care for over 115,000 patients in some 1,500 facilities across the country. Nearly seventy-five percent of dialysis patients have Medicare as their primary insurance. Approximately forty percent of those are dually eligible for Medicare and Medicaid.

An important component of the Medicare prescription drug program is evaluating its effectiveness and efficiency. We generally agree with the stated purposes of using the Part D claims data; however, we have the following comments for the Agency to consider:

1. In the "Information to be Collected" section, we note the discussion of confidentiality requirements for external researchers, but we do not see any discussion of how beneficiaries will be notified that their claims data may be shared with external agencies and/or researchers to accomplish one or more of the stated purposes. Specifically, what are the requirements under HIPAA for notifying Medicare beneficiaries that their personal health information will be shared, with whom, and for what purpose? We do note that you discuss confidentiality requirements for external researchers.

2. The "Purpose of CMS Collecting Information" section does not include evaluating the impact of the coverage gap (donut hole) as a purpose for collecting information. Because the gap is of great concern to many Medicare beneficiaries, we propose that CMS evaluate how many Medicare beneficiaries are reaching that point in the benefit, at what period during the year they are reaching it, and how long they are in the gap before spending their way to the catastrophic coverage level.

3. One of the purposes of the Part D claims data is to create a chronic care warehouse to facilitate research for specific chronic illnesses that will focus on improving the quality of and reducing the cost of health care services. We would like to encourage CMS to include chronic kidney disease (CKD), or End Stage Renal Disease (ESRD), as one of the chronic illnesses in the

Fresenius Medical Care

database. The National Kidney Foundation has isolated common medications taken by CKD patients and updates information about which Part D plans cover these common medications on a monthly basis (see www.kidneydrugcoverage.org). This has been helpful information for CKD patients, and we encourage CMS to continue to focus on this vulnerable population.

4. We support evaluating the experience of Medicaid beneficiaries as their pharmacy coverage changes from Medicaid to a private Part D plan. It is important to know whether the issues the Medicaid beneficiaries experienced in changing from Medicaid to Part D coverage, such as not having adequate transition time to receive their medications, were isolated to the beginning of the Part D program or whether they are ongoing issues that need more attention. We also support using the information to compare medication costs of Medicaid beneficiaries before and after Part D implementation.

5. We support using information from Part D claims data to continue to evaluate and monitor the Part D plans, including customer service and Medicare beneficiary complaints.

6. In response to your request for comments about "Beneficiary Access to Part D Data", perhaps this could be integrated into the new MyMedicare.gov website where beneficiaries can go for personalized information about their Medicare benefits. Some helpful information for Medicare beneficiaries to access about their Part D plans could include links to their Part D plan and formularies, instructions for prior authorization requests, and a history of drugs purchased for the current calendar year.

Thank you for the opportunity to submit comments. If you have any questions, or if I can be a resource for questions about the ESRD patient population, please contact me.

Sincerely,

Wendy Funk Schrag

Wendy Funk Schrag, LMSW, ACSW
Director of Advocacy and State Government Affairs
Fresenius Medical Care
625 Medical Center Drive
Newton, Kansas 67114
316-841-5245
wendy.schrag@fmc-na.com

Submitter : Gary Persinger **Date:** 12/18/2006

Organization : National Pharmaceutical Council

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

see attachment

CMS-4119-P-101-Attach-1.DOC

NATIONAL PHARMACEUTICAL COUNCIL, INC.
Quality Through Research

December 18, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Attention: CMS–4119–P

Comments of National Pharmaceutical Council on CMS Proposed Rule Regarding Medicare Part D Data

The National Pharmaceutical Council (NPC) appreciates this opportunity to comment on proposed rule CMS-4119-P. The NPC is a not-for-profit research and education organization supported by 20 pharmaceutical companies. Since 1953 NPC has sponsored a variety of research and education projects aimed at demonstrating how the appropriate use of pharmaceuticals can improve both patient treatment outcomes and the cost-effective delivery of overall health care services.

As a research-based organization, NPC looks forward to the opportunity to support research on the Part D benefit and its effects, using data that for the first time connect Medicare patients' use of pharmaceuticals to physician visits, hospital use, and other medical services. These data will provide a powerful new resource for examining health care provided to the Medicare population in a comprehensive framework that links together the primary medical care services that each patient uses in addressing health care needs. Because of our role in conducting and supporting research, our comments focus narrowly on access to data for entities outside CMS, and more specifically, access for external researchers.

Our primary concern is that all legitimate research requests for access to Part D and other Medicare data should be evaluated on the same, consistent basis. Research that contributes to Medicare beneficiaries' health and efficient operation of the Medicare program can be conducted by commercial entities and organizations funded by commercial entities and should be permitted under the same terms and conditions to which other external organizations are subject.

Sharing Data with Entities Outside CMS

The collection of Part D claims information and linkages to other Medicare data, especially Parts A and B, create a unique research database that will foster a wealth of research questions and projects regarding the effects of the Medicare Part D drug benefit. Although researchers have made ample use of Part A and Part B data, many research questions previously could not be addressed because linkable data on one of the most used outpatient services -- prescription drugs -- were not available. The proposed rule addresses that shortcoming and makes it possible to address important research questions that in the past have gone unanswered for lack of an appropriate database.

1894 PRESTON WHITE DRIVE, RESTON, VIRGINIA 20191-5433 (703) 620-6390 FAX (703) 476-0904
www.npcnow.org

The addition of drug claims information to the data available on the Medicare program makes Medicare data more meaningful not only to government and academic researchers, but also to researchers in the pharmaceutical industry and other commercial entities. Pharmaceutical companies routinely conduct sound and credible research – they would not be able to obtain FDA approval for their products without it. Data that reflect how products are actually used by patients in the real-world, outpatient setting can provide new insights and sometimes uncover problems that were unforeseen and undiscovered in controlled research studies.

We believe that the same policies CMS has already established regarding access to and use of other Medicare data will work well for access and use of Part D data alone, as well as broader linked Medicare datasets for each patient. The policies outlined in Criteria for Review of Requests for CMS Research Identifiable Data[1] require a specific research protocol that includes the research design and the specific objectives and importance of the study. In approving any request for data, CMS requires description of hypotheses, data limitations, measures to be applied to protect the privacy of Medicare beneficiaries, analytic methods, timing, and the qualifications of key staff. To be approved, a project must be aimed at improving the program or services provided to beneficiaries. Further, each requestor must sign a data use agreement that limits use of the data to the specific research purpose stated in the agreement and specifies conditions under which data are to be destroyed or returned to CMS upon completion of the research. Finally, the requestor must show the necessary experience and expertise to conduct the research.

We believe that a data request from any individual or organization meeting these conditions and requirements should be reviewed and judged equitably without regard to the commercial status of the funding source for the study. However, current policy reflected in CMS review criteria Number 7 indicate that "CMS has historically denied data requests from requestors wanting to evaluate the impact of prescription drugs if a pharmaceutical company finances the study."1 The ability of individual pharmaceutical firms or organizations supported in whole or in part by such firms to fund research using Medicare data should not be restricted or denied simply because of their status as or funding from commercial entities.

All data requests should be approved or denied on the same set of equitable criteria. We recommend that this clear bias against pharmaceutical company supported research be deleted from the CMS review criteria. In any event, if this statement were to remain a part of the CMS review criteria, we are concerned that clearly non-commercial, health services research supported by our organization might be denied access to Medicare data, especially data related to prescription drug use, solely because our organization and its research are funded by pharmaceutical companies.

If you have any questions regarding our comments, please feel free to contact me at 703-715-2757or gpersinger@npcnow.com.

Sincerely,

Gary Persinger
V.P., Health Care Systems

[1]http://www.cms.hhs.gov/PrivProtectedData/02_Criteria.asp

Submitter : Mr. Pete Stark **Date:** 12/18/2006

Organization : Ways & Means Subcommittee on Health

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-102-Attach-1.DOC

December 18, 2006

The Honorable Leslie V. Norwalk
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Re: File Code CMS-4119-P

Dear Ms. Norwalk:

As Ranking Member on the Committee Ways and Means, Subcommittee on Health with jurisdiction over Part D, I respectfully submit the following comments on the proposed rules (CMS-4119- P) entitled "Medicare Program; Medicare Part D Data," issued October 18, 2006.

I applaud your effort to clarify CMS's statutory authority to collect Part D data necessary to evaluate the program and its overall effectiveness. I urge you in the final rule to collect all data necessary from all available sources consistent with the authority granted under 1860D-12(b)(3)(D) of the Medicare Modernization Act (MMA). I look forward to using this information in making future policy decisions about the program and welcome the opportunity to work with CMS in the event any additional legislative authority is needed to ensure adequate information is available for these purposes.

Information to be collected
The proposed rule allows claims data, now collected for payment purposes, to be used for research, analysis, reporting and other public health functions. The statute is clear that CMS can use claims data for these purposes. Moreover, I urge CMS to access all the Prescription Drug Event (PDE) data necessary, and to clarify your ability to add elements to the PDE claims data. Specifically I request you require plans to report the net price (after all discounts and rebates) paid by the plan for the drug dispensed.

Purpose of CMS Collecting Information

While it is appropriate in the regulations posted by CMS to highlight for what purposes CMS might collect PDE data, CMS should in no way limit its use to only the purposes stated in the rule. Moreover, the list of purposes for which the data would be used for should be expanded to include program integrity. While CMS staff has assured me that program integrity is always an allowable purpose, it is important to clarify in the final rule that PDE data can be used at anytime to protect the program. It is impossible to properly monitor the program and ferret out waste, fraud, and abuse if the agents charged with program integrity do not have immediate and unfettered access to the claims data.

Sharing Data with Entities Outside of CMS

Many entities, both inside and outside the government, will need and want access to the Part D claims data. Some of these entities deserve broad access with few restrictions, while others should be denied access altogether. I urge CMS to use the final rule to implement a tiered system of access to PDE data taking into account the need for data and opportunity for abuse among: 1) other government entities; 2) contractors and researchers under direct contract with CMS or a government entity; and 3) outside researchers.

The proposed rule must construct a more robust system of deciding who has access to PDE data under what circumstances. The final rule should clearly state that all applicable government agencies, including Congressional support agencies such as the Congressional Budget Office (CBO), Medicare Payment Advisory Commission (MedPAC), Government Accountability Office (GAO) and Congressional Research Service (CRS), will be allowed broad access to claims data in a timely fashion without submitting requests for multiple data use agreements. Data use agreements with government agencies must not be limited to individual investigators, or specific research purposes.

This data should also be made available to state Medicaid Directors, for purposes of monitoring and researching the dual-eligible population. With the transfer of the dual eligibles from Medicaid to Medicare, neither the beneficiary's Medicare Part D plan nor Medicaid now possess a complete profile of a patient's drug regimen. This is likely to lead to increasing instances of adverse interactions and inappropriate care, further complicating recent state efforts improve care coordination. Therefore, I request that CMS amend the proposed rule to provide states with access to the drug utilization and spending data collected by the Medicare Part D prescription drug plans, as well as any other data necessary for states to effectively coordinate the care of the dual eligibles.

There are many contractors "outside of CMS" that should be granted access to Part D claims data. Consistent with our request that claims data be used for program integrity

purposes, the final rule should clarify that Medicare Drug Integrity Contractors (MEDICs) can obtain PDE data where necessary to fully investigate complaints and fraudulent claims. Other contractors conducting research funded by CMS, and other government agencies should also enjoy broad access to the data, but data use agreements must be strictly enforced to ensure contractors do not share data with other parties.

Another concern with the proposed rule is the use of PDE data by outside researchers that may attempt to use the information for dubious purposes. Organizations with strong proprietary interests should not have access to the PDE data. For example, pharmaceutical manufacturers hoping to use the data to sell particular drugs to prescribing physicians should not be allowed to use the data for that purpose. I believe the final rule should strike an appropriate balance between giving bona fide researchers access to data while denying access to proprietary interests. The final rule should specifically deny PDE data access to drug plan sponsors, pharmaceutical manufacturers, and other industry data collection entities (e.g. IMS Health) that sell market research and sales data.

Limitations
The final rule should continue to make clear that CMS has the ability to collect any data otherwise allowed by statute, as well as any data if deems necessary to manage Part D.

Sincerely,

Pete Stark
Ranking Member
Ways & Means Subcommittee on Health

Submitter : **Date: 12/18/2006**

Organization : **HMO Cancer Research Network**

Category : **Health Plan or Association**

Issue Areas/Comments

Applicability

Applicability

On behalf of the thirteen- site NCI funded HMO Cancer Research Network (CRN), these comments are in broad support of the proposed rule (42CFR Part 423; File code CMS-4119-P) regarding access to Medicare Part D Data. The proposal articulates well the pressing need to use Medicare Part D claims to analyze, report, and conduct research to improve the public health of Medicare beneficiaries. The proposed rule adequately balances information needed to protect/ improve the public health and privacy concerns of beneficiaries. Safeguards currently in place on use of claims information for research will adequately protect the confidential private health information of beneficiaries.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

Purpose of CMS Collecting Information

In addition to the 4 bullets in this section regarding reporting to Congress, conducting evaluations of the Medicare program, making legislative proposals, and conducting demonstration projects/making recommendations for improving the Medicare program, an implicit purpose of using these data for analyzing the variation in use, outcomes, and cost consequences of prescription medications under actual conditions of use.

With respect to cancer treatment, a new wave of highly expensive regimens that include targeted therapies and colony stimulating factors to be given alongside traditional chemotherapy agents have been introduced to the US market during the past few years. Increasingly, cancer drugs are being developed for self-administration, and those drugs are frequently among the most sought-after by oncologists and patients. The high costs of these new agents and technologies often force clinicians and patients to make difficult decisions on what to implement in practice with insufficient information on costs and outcomes. It is essential to understand uptake of use, economic consequences, effectiveness, and safety associated with self administered pharmaceuticals and other patient reported outcomes. The Part D benefit may spur the development of new medications that patients may take orally, self-administer, or change the model of care delivery around cancer-specific pharmacotherapy.

Complicating cancer care further are changes in how specific therapies are reimbursed, which may change care delivery pattern. Due to reimbursement changes included in the 2003 Medicare reform bill, there has been a shift from administering cancer therapies in infusion centers to community hospitals. The economic and clinical consequences of changes in benefit structures, reimbursement, and delivery of cancer care are of great importance to payers and patient.

Although language describing the importance of collecting data for this purpose is contained in this proposed rule, it appears predominantly under the section regarding Sharing Data with Entities Outside of CMS. While it is important that this language be present to justify the importance of these data to outside agencies given the missions of NIH, FDA, AHRQ, CDC, HRSA, and academic researchers, the overarching purpose of protecting the health of Medicare beneficiaries argues that it also should be contained in the section regarding Purpose of CMS Collecting Information . It is CMS s purpose to protect the health of beneficiaries, even though other agencies and external researchers may operationalize that purpose. The CRN represents an important sector of healthcare and a significant resource for research on cancer prevention, early detection, treatment, long-term care and surveillance. Should Part D data be released, the CRN is poised to conduct research studies using Part D data to address many of the issues noted above.

Information to be Collected

Information to be Collected

We were very pleased with the proposal to make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality. [page 61453, column 1] The existing terms and procedures have made possible research on questions that have contributed to very significant improvements in the public health and have spurred other types of research.

It is for this reason that we wish to explicitly comment, as requested, on whether [CMS] should consider additional regulatory limitations for external researchers beyond existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released. [page 61453, column 1] Without access to Part D data, we will lose the ability to track use of medications among the most vulnerable populations (e.g., the dually eligible) as they transition into the drug benefit. Thus, it will be important for the databases to use unique identifiers that can be linked to the individuals actual identities when there is an approved need to do so.

We believe that the existing terms and procedures are sufficient protection because of the professional and ethical codes of conduct guiding academic research, peer review process, and rigor required of data centers under the data use agreements. There have been no published incidents where CMS data have been leaked, let alone had adverse consequences. Thus these terms and procedures have stood the test of time.

We imagine that industry sponsorship and provider profiling may be two sources of concern behind this particular request for comment. Any research, regardless of sponsoring organization, will still need to stand the test of peer review. Thus, industry sponsorship of research studies should not be of special concern or require additional regulatory limitations. Provider profiling (identifying individual providers based on measures of the care they provide) has long been a concern

of CMS. The current terms and procedures insure that those requesting data agree to not identify individual providers or release reports identifying individual providers. The DUA includes penalties for not following the letter of the DUA and it seems that commercial misuse for provider profiling would be included under these procedures.

The availability of Medicare Part D data, which can be linked with other data on Medicaid and Medicare services, is essential to AHRQ, CMS, FDA and NIH being able to carry out their respective missions. The drug benefit data provides the largest person-specific database on medication use among elderly and disabled in the U.S. When linked with other Medicare health information (e.g., hospitalizations), it can be used by researchers to examine drug safety (e.g., targeted chemotherapy agents), the effectiveness of medications in real-world settings, the effects of drug coverage and cost containment (e.g., cost-sharing) on Medicare costs and the health of vulnerable elderly and disabled, and test new interventions to improve medication prescribing and adherence. Such data will not only generate important discoveries, but will be vitally important to CMS, in helping to increase the effectiveness (especially in high-risk populations such as the mentally ill) and moderate the costs of the drug benefit over time.

Limitations

Limitations

We completely support the use of Part D claims data for projects involving the development of personalized beneficiary medication history records for the use of Medicare beneficiaries themselves. CMS should look to a Medicare pilot demonstration project conducted by the United Mine Workers Health and Retirement Fund for a model of such a project.

CMS-4119-P-103-Attach-1.DOC

Draft of CRN's Response to the CMS Proposed Rule Regarding Medicare Part D Data November 15, 2006

On behalf of the thirteen- site NCI funded HMO Cancer Research Network (CRN), these comments are in broad support of the proposed rule (42CFR Part 423; File code CMS-4119-P) regarding access to Medicare Part D Data. The proposal articulates well the pressing need to use Medicare Part D claims to analyze, report, and conduct research to improve the public health of Medicare beneficiaries. The proposed rule adequately balances information needed to protect/ improve the public health and privacy concerns of beneficiaries. Safeguards currently in place on use of claims information for research will adequately protect the confidential private health information of beneficiaries.

"Purpose of CMS Collecting Information"

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beneficiaries argues that it also should be contained in the section regarding "Purpose of CMS Collecting Information". It is CMS's purpose to protect the health of beneficiaries, even though other agencies and external researchers may operationalize that purpose. The CRN represents an important sector of healthcare and a significant resource for research on cancer prevention, early detection, treatment, long-term care and surveillance. Should Part D data be released, the CRN is poised to conduct research studies using Part D data to address many of the issues noted above.

"Sharing Data with Entities Outside of CMS"

We were very pleased with the proposal to "make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality." [page 61453, column 1] The existing terms and procedures have made possible research on questions that have contributed to very significant improvements in the public health and have spurred other types of research.

It is for this reason that we wish to explicitly comment, as requested, on "whether [CMS] should consider additional regulatory limitations for external researchers beyond existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released." [page 61453, column 1] Without access to Part D data, we will lose the ability to track use of medications among the most vulnerable populations (e.g., the dually eligible) as they transition into the drug benefit. Thus, it will be important for the databases to use unique identifiers that can be linked to the individuals' actual identities when there is an approved need to do so.

We believe that the existing terms and procedures are sufficient protection because of the professional and ethical codes of conduct guiding academic research, peer review process, and rigor required of data centers under the data use agreements. There have been no published incidents where CMS data have been leaked, let alone had adverse consequences. Thus these terms and procedures have stood the test of time.

We imagine that industry sponsorship and provider profiling may be two sources of concern behind this particular request for comment. Any research, regardless of sponsoring organization, will still need to stand the test of peer review. Thus, industry sponsorship of research studies should not be of special concern or require additional regulatory limitations. Provider profiling (identifying individual providers based on measures of the care they provide) has long been a concern of CMS. The current terms and procedures insure that those requesting data agree to not identify individual providers or release reports identifying individual providers. The DUA includes penalties for not following the letter of the DUA and it seems that commercial misuse for provider profiling would be included under these procedures.

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"Beneficiary Access to Part D Data"

We completely support the use of Part D claims data for projects involving the development of personalized beneficiary medication history records for the use of Medicare beneficiaries themselves. CMS should look to a Medicare pilot demonstration project conducted by the United Mine Workers Health and Retirement Fund for a model of such a project.

Submitter : Ms. Patrica Wilson **Date:** 12/18/2006

Organization : Associates & Wilson and TRICAST

Category : Health Care Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachments

CMS-4119-P-104-Attach-1.TXT

CMS-4119-P-104-Attach-2.TXT

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10400 W. Innovation Drive, Suite 100
Milwaukee, WI 53226-4826
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greg.rucinski@tricastinc.com

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

This letter and the attached Exhibit 1 are being submitted electronically to www.cms.hhs.gov/eRulemaking as a Microsoft Word document. The submission was made before the deadline of 5PM on December 18, 2006.

December 18, 2006

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Re: CMS-4119-P.
Submitted to http://www.cms.hhs.gov/eRulemaking

Dear Sir or Madam:

This letter and the attached Exhibit 1 constitute the collective comments of TRICAST and Associates & Wilson on the Medicare Part D Data proposed rule cited above. Comments are submitted on:

- Information to be Collected
- Purpose of CMS Collecting Data
- Sharing Data with Entities Outside of CMS, and
- Beneficiary Access to Part D Data.

TRICAST and Associates & Wilson collaborated on these comments. Both firms, and the individuals which comprise them, focus on the complex world of drug management and claim processing. We have each identified many opportunities for improvement that can exist in an electronic infrastructure because we know the systems inside and out. We understand what is possible, but we also understand what is not done. We are of like mind in that we commit to doing well by continuous improvements using systems and their input and output to improve patient care and eliminate waste. We have approaches that are complimentary.

We applaud CMS's efforts in these proposed rules to resolve any statutory ambiguity about the rights of the Secretary of HHS to collect data, and to provide specifics about how the data will and may be used.

We believe that the Secretary has the right and duty to collect and use the data to properly carry out his responsibilities. Data is not only critical to fulfilling many, if not most, of the requirements under MMA, it is also critical to patient safety and quality care. Pharmacy is unique in terms of the speed with which, and the point at which, data are captured. Pharmacy has always been technology-based, with the ability to turn data into useful information efficiently and less expensively than the manual operations of other entities. Medicare's entry into

pharmacy on a much larger scale presents opportunities for new and different approaches to managing health care. It all hinges on collecting, using and linking patient data to improve care.

Comments on specific sections of the proposed rule follow.

***Issue identifier*: A. Information to be Collected**

The proposed rules state that CMS would be collecting the same claims information collected under section 1860D-12(b)(3)(D). The attached Exhibit 1 lists the 37 data elements that are currently collected for 2006 and are the subject to the proposed rule. Exhibit 1 also contains the intended use of each data element and offers *Notes* , for your consideration, on possible uses. We also propose adding several other data elements that are available in a pharmacy in electronic form and could be transmitted to the Pharmacy Benefit Manager (PBM) or are already in the PBM's files but are not part of the 2006 CMS required data elements.

The technology that PBMs use captures important data that can easily be transformed into useful information. Current uses vary from: determining eligibility for benefits, to what are the covered benefits, to prices to be paid to pharmacies and fees to be collected from plan members. But with more data, more is possible. For these reason, some employers and PBMs are looking to use the existing and new information in creative ways to manage their drug and medical plan and to improve the quality of care for patients. HHS should understand the possibilities and expand on them as the basis of coverage decisions and efficiencies.

Here are the data elements that are currently electronically available in a pharmacy or a PBMs system but are not a part of CMSs 2006 submission. :

- ***Sig-*** The directions for use (e.g. *bid*, short for *bis in die* and meaning for us non-Latin scholars twice a day) should be included as part of the electronic claim, along with the quantity, and the days supply. This is hand written on a prescription by the doctor and it is a data element in all pharmacy systems. However it is not currently transmitted to the PBM from the dispensing pharmacy- whether mail, retail or specialty. It is only used to print the bottle or box label telling the patient how to take the medicine.

  The *sig* can be used to correlate the quantity dispensed for a specific duration of time (say 30 days) to the number of pills being dispensed. Knowing the sig allows additional DUR to check against the drugs dosing recommendations to determine if it is reasonable. For example, if 30 pills are being requested for 30 days of treatment, yet dosing guidelines are for multiple pills a day, there is a shortfall or suboptimal. In addition, too much product is just as much an issue as too little. In both cases, the sig makes possible a simple edit using electronically available data and supports the goal of appropriate care. Further if the ultimate sharing of costs between beneficiaries and CMS is a flat dollar copay design, this is an important edit to preclude stockpiling and other fraud.

- ***COB Indicator-*** Simply stated this field would indicate whether the claim has already been submitted to another program or plan that may be the primary payor. This indicator could assist in the assessment of appropriate Part B covered items.

- ***Other Coverage Code***-This field can be used to identify the specific carrier providing primary coverage in order to verify appropriate an alternate primary carrier or PDP.

- ***Prior Authorization***- This field is used to indicate whether an authorization was placed on the claim submission by the PBM or carrier in order to override a coverage rule.

- ***Prior Authorization Reason Code***- This field is used to indicate the reason a prior authorization was placed on the claim to override a coverage rule as well as by whom the authorization was made.

- ***Pharmacy Override Code***- This field can be used to assist in determination of appropriate data collection in support of pharmacy provider input relative to patient interviews and assessments.

- ***Claim Type***-This field will allow an indication of whether the claim is being submitted by a pharmacy (electronic) or a subscriber (paper).

- ***Adjustment Date***-This field is the date the adjustment was processed, this date will allow a retrospective analysis of reversals and credits to claims in order to accurately portray any change in TROOP and associated accumulations to the plan financials.

All of the above items exist in electronic form, and if submitted to CMS in the future, can facilitate improvements in patient care and/or the speed with which and the cost of auditing claims for appropriateness or in spotting fraud, waste and abuse.

We are also proposing one new data element – the diagnosis code. This data element is not currently in a PBM system other than what might be collected during the Prior Authorization process or if the drug was dispensed through a Specialty Pharmacy operation. However, it is collected on drugs covered under Medicare Parts A and B and for all other services and supplies covered under Medicare. The data element is the diagnosis code. A space has been reserved in the NCPDP format. We refer to the diagnosis as **Dx**. In Associates & Wilson's previous comments to HHS as far back as 2002, Associates & Wilson urged HHS to make it a requirement on every script. There it was referred to it as **Dx on Rx.** TRICAST also urges consideration of Dx on Rx. Here are potential uses for the diagnosis code:

- ***Dx- 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, including concurrent DUR, on dosage adjustments and other important warnings and cautions. It is also impossible to efficiently identify claims for uses that are not supported by any published evidence of effectiveness.

- ***Different Drugs, Different Uses, Confusing Names***- Sometimes medication is selected in error because the names are similar with slightly different spelling or pronunciation. Dx

allows prescribers, dispensing pharmacists, PBMs – and more importantly – systems to check the diagnosis code against the dosing specific to the patient's condition.

- ***Information on Eligibility and Benefits-*** *Dx* has the benefit of helping to determine eligibility for prescription plan coverage under A, B or D. Some prescription drugs have multiple uses. Some of those uses are eligible for coverage under Medicare Parts A and B 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 under Part D have been met.

- ***Information on drug-drug interactions, warnings or cautions and when indicated, dosage adjustments 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 (IOM) advocates "designing systems that make it hard for people to do the wrong thing and easy for people to do the right thing". *Dx* added to the reported data elements is a system design feature that meets the Institute's criteria and facilitates the Medicare e-prescribing requirement to provide information on interactions, warnings or cautions and dosage adjustments.

- ***Information on the availability of lower cost, therapeutically appropriate alternatives (if any) for the prescribed drug-*** This is required by the statute. Without knowing the Dx, it is difficult to offer effective alternatives.

Dx is supported by adequate industry experience and doesn't require pilot testing. While pharmacy benefits are generally 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 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(recently rectified by NCPDP) However, during the 6 year period when *Dx* 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.

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 potential savings in the hundreds of millions to Medicare and Rx drug benefit plan sponsors.

***Issue identifier*: B. Purpose of CMS Collecting Information**

We agree that HHS needs to use Medicare Part D prescription drug related data for a wide variety of statutory and other purposes including the four stated ones:

- Reporting to the Congress and the public on the overall statistics associated with the operation of the Medicare prescription drug benefit
- Conducting evaluations of the Medicare program
- Making legislative proposals with respect to the programs administered by CMS including the Medicare, Medicaid and State Children's Health Insurance Program; and
- Conducting demonstrating projects and making recommendations for improving the economy, efficiency or effectiveness of the Medicare program.

At the most basic level, we purport that without the data collection there would be no way for CMS to determine what is and what is not an eligible claim under Part D. That is because coverage decisions involve applying the rule set to varying situations. Sometimes a prescription claim meets Medicare's definition of coverage while other times that same claim is not covered because it may be considered experimental, cosmetic, or not for a medically accepted indication. Reviewing these decisions requires reviewing the claims data.

In addition, the Medicare Modernization Act (MMA) requires Pharmacy Drug Plan (PDP) sponsors to have in place:

- cost-effective drug utilization management programs,
- quality assurance measures and systems to reduce medication errors and adverse drug interactions and improve medication use,
- medication therapy management programs, and
- programs to control fraud, abuse and waste.

Again, evaluating these programs requires of review of claims data.

CMS requested comments on whether there should be any limitations on data when shared for purposes other than fulfilling CMS's **responsibility to administer** the Part D program. We add emphasis here because it depends on what CMS means by administer. If it is to promote safety, pay for what beneficiaries need, but not everything that they want or that Doctors want to prescribe, then we say that there should be no restrictions on data. We accept that 2006 is a transition year. However, we suggest that CMS or claim reviewers need to have a high level of expertise on how claims *actually* process. We offer the following areas for your consideration of specific examples of processing problems that are widespread. Most will be surprised, even shocked, to learn that for most PBMs, current processing protocols allow *all* of the following claims to process on a *regular basis*:

- Processing claims, without a duplicate drug DUR edit, for the same narcotic drug where the NDC varies by strength in such an amount that the maximum dose for the drug is exceeded.
- Processing claims for a 90 day supply of sleeping medication even though the FDA approved drug label limits use to a 30 day supply.
- Processing claims for a brand name medication when its generic equivalent also processed so that the dose is doubled.
- Processing claims where a moderate or major drug to drug interaction is documented without an intervention on the part of the PBM- other than "to rely on the professional integrity of the pharmacist".
- Failing to send a drug allergy message for a drug containing sulfa to a retail pharmacy when the PBM knew from its mail order patient profile that the member was allergic to sulfa. Some PBMs argue that each dispensing pharmacy maintains its own allergy records and that it, as the PBM, has no obligation to share what it has captured through its mail service facility.
- Processing claims that do not meet the articulated evidence- based coverage criteria for the Prior Authorization process. It is not just the coverage criteria that are important but the way in which the PBM garners the information. Secret handshakes abound.
- Processing claims after the PA has been approved where a starting dose is outside of the recommendations for appropriate use and in a quantity that is excessive or suboptimal. Since the PA process for many only judges whether the drug is covered or not, there is no look at the other factors such as strength or frequency.

Most of these problems can be addressed by reviewing the data and having a clear understanding about:

- how claims actually process,
- how the various DUR modules work (alone and with each other), and
- what patient data is- or could be- available for use.

But it is all doable and involved in the administration of Medicare. The Secretary has broad responsibilities to do just that … plus a whole lot more.

***Issue identifier*: C. Sharing Data with Entities Outside of CMS**

CMS proposes adding section 423.505(f)(5) that would specify that they could use and share the claims information collected under 423.5(f) with both outside entities and other government agencies, without regard to any restriction included in 423.322(b). We agree with this proposal and believe it is critical to improving the U.S. health care system. A review of the list of claims that will process on a routine basis that was given in the previous example shows the need for a detailed review of the data by many who have specialized information to bring to the task of improving care while maintaining the viability of the coverage.

The Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations are causing both head scratching and some steps backward in the managed pharmacy area. PBMs and retail pharmacies are at odds about what data they can and should capture as part of the electronic claim submission in light of HIPAA. Some are posturing under the guise of outright prohibition of even the most basic data. It may however represent a desire to spend less time on entering data. But data specific to the individual is necessary not only to determine if the drug for Aunt Sophie is an eligible claim under the health plan, but also to determine if it is safe and appropriate. We presume that clarification is needed since it was never your intent to force coverage of ineligible charges (an ERISA violation) or to process claims that may do harm. We assume that the Institute of Medicine's (IOM) ideas as outlined in its reports (To Err is Human and Crossing the Quality Chasm) will proceed unimpeded by HIPAA. Their thrust, like ours, is for data-driven systems, supporting physicians, to improve quality of care.

Other Government Agencies

CMS requested guidance on how they can best serve the needs of other agencies through the sharing of information it collects under section 1860D-12(b)(3)(D) of the Act while at the same time addressing the legitimate concerns of the public and of Part D plans that CMS appropriately guards against the potential misuse of data in ways that would undermine protections put in place to ensure confidentiality of beneficiary information, and the nondisclosure of proprietary data submitted by Part D plans.

The Part D plans proprietary data consists of negotiated prices for drugs, the negotiated dispensing fees and the manufacturer rebates on specific products. What is also proprietary is the cost basis for each customer, since all do not receive the same terms. Only the ingredient costs and the dispensing fees are data elements at the beneficiary claim level. This is the data that would be passed for review. The rebates are not shown at the claim level (by drug or by beneficiary), but are treated as an estimated total offset to the monthly filings. Therefore, we are not talking about rebate agreements. While PBMs might claim that all is proprietary, there is a relatively narrow range of discounts and fees, other than the generic prices and when they are applicable. Further the fee, without knowing the other administrative charges not included on the detailed data set, is adding additional complications to the analysis. In other words the factual statements about the bottom line net cost to a customer are sufficiently muddied to protect the PBMs. They are masters at doublespeak. We conclude that no restrictions are needed to protect PBM proprietary information.

External Researchers
CMS requested comments on the proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health. CMS asked for comments on whether it should consider additional regulatory limitations for external researchers beyond the existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.

We believe that no additional use agreement protocols are needed. However, we would urge CMS to consider in granting access for data for research, the both the immediacy and how patients, the Medicare Trust Fund and other parties will benefit from the project. This is not just about research for research sake. It is also about improving care, improving safety, and eliminating waste from the system.

***Issue identifier*: D. Beneficiary Access to Part D Data**
CMS is considering the use of Part D claims data for projects involving the development of a personalized beneficiary medication history record that would be accessible by Medicare beneficiaries. CMS requested comments on this proposed use of Part D data collected under the authority of section 1860D-12(b)(3)(D) of the Act.

We accept that a patient drug profile is a useful tool for beneficiary access. CMS contemplates using Part D drug data. That is of limited value since the usefulness is to have a record of *all* of the drugs that the beneficiary takes, regardless of the site of administration, or Parts under Medicare where the claim was paid. And to be the most useful, it should be updated as drugs are dispensed. CMS also now contemplates that the beneficiary can release the patient drug profile to any individual or institution. However, we urge CMS to establish procedures where the data will be automatically available to other health care practitioners and institutions. For example, the beneficiary may be unable to direct that the data be sent because they are unconscious or confused because of a drug's side effect.

- Part A covers drugs administered in a hospital while the beneficiary is receiving treatment. They should be combined into the patient drug record. Having the combined drug record available to a hospital- especially the emergency room- tells the treating physicians what other drugs the beneficiary is likely to have in their body because of a recent Rx service date or an extended supply. In a 20 year old program (*Rx Watch*), this feature saved lives. Granted it was before HIPAA, but the plan member was given a card to keep in their wallet. And if they were admitted to the hospital, they could call the 24/7 telephone line to get the drug information. As hospitals work on order entry and drug review systems for their institutions, CMS can facilitate improvements by promoting systems that are more than a billing function.
- Part B covers selected drugs that are administered incident to a physician's service as long as the physician procures the drug. The Competitive Acquisition Program (CAP) approach met with resistance and was delayed and the rules issued on what can be submitted as a Part D drug moves drugs that would otherwise be B drugs to D solely because the beneficiary picked it up in a pharmacy or had it mailed to their home. The physician then administers the drug and is paid for the administration of the drug. This is a quirky mess, but the drug record should contain all of the drugs whether under B or D. The physician in

his office should have access to the combined drug record since many of the specialty drugs they administer interact with other drugs prescribed by other treating physicians.

- We are not submitting comments on sections **E. Applicability** or **F. Limitations.**

MMA provides new opportunities to help healthcare providers integrate pharmacy to manage the health of Medicare beneficiaries. Securing data elements that are already available, in a format that is universally understood and easy to use, provides the single greatest non-clinical opportunity for healthcare improvement in recent years. And, experience has shown that CMS' leadership and standards will be adopted for non-Medicare plan participants – to improve healthcare for all Americans. Thus, we believe it is critical that any standard reflect the promise of tomorrow's healthcare system, rather than the limitations of today.

The firms, Associates & Wilson and TRICAST, and its consultants have collaborated on this response. Our collective experience and capabilities uniquely positions us to emphasize data that is readily available, diagnose shortfalls in data use, and visualize and implement solutions that are practical and cost-effective. Our expertise is converting data to information – and in turn, converting information to knowledge – for the benefit of healthcare providers and the patients they serve. As you contemplate our comments, you note our core belief that pharmacy data has enormous potential in promoting, quantifying and improving patient care.

Pharmacy data is factual, reliable and powerful. In part the power comes from it roots. Pharmacy data has been electronically gathered and adjudicated in a real time environment for over a decade- in well defined technological standard protocols. We believe there is great potential in the use and distribution of this data, especially with expanded fields and better precision of patient, claim, and plan information. This information is readily and normally available in all pharmacy benefit programs and is presently exchanged within defined business relationships.

We believe that it is everyone's best interest to use the available data to stimulate, compare and communicate quality improvement initiatives to this program, healthcare providers, and Medicare beneficiaries.

Sincerely,

Greg Rucinski
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Patricia L. Wilson
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