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

**Organization :** Academy of Managed Care Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

GENERAL

GENERAL

See attached.

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

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

**Organization :** Academy of Managed Care Pharmacy

**Category :** Pharmacist

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment.

CMS-4119-P-72-Attach-1.DOC

AMCP Academy of Managed Care Pharmacy



December 18, 2006

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

**Subject: Medicare Part D Data [File Code CMS-4119-P]**

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide comments to the Centers for Medicare & Medicaid Services (CMS) on the Medicare Part D Data proposed rule (Federal Register, Volume 71, Number 201; October 18, 2006) which would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting and public health functions.

AMCP is a national professional association of pharmacists who have responsibility for managing prescription drug benefits in the private sector for health plans and PBMs and in the public sector through such agencies as the Department of Veterans Affairs, the Department of Defense and state Medicaid programs. Our 5,000 members provide comprehensive services to the over 200 million Americans served by managed care organizations.

Purpose of CMS Collecting Information

As CMS describes in the draft guidance, the agency needs the ability to use the Medicare Part D prescription drug event (PDE) data, reported by prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs), for reporting to Congress and the public on the overall statistics associated with the Medicare prescription drug benefit, evaluations of the program, making legislative proposals and conducting demonstration projects. The Academy agrees that this data is of critical importance to the development and evaluation of the Medicare Part D benefit. Prescription drug utilization information will allow future projections about the Part D prescription drug benefit to be more accurate. AMCP supports CMS' use of the PDE data currently available to CMS for purposes other than payment reconciliation.

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

Sharing Data with Entities Outside of CMS

In the PDE prescription drug data reported by prescription drug plans (PDPs) and Medicare Advantage plans (MA-PDs), CMS has information that can be incredibly valuable for various purposes including evaluating the Medicare prescription drug benefit, performing demonstration projects and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs. This data will be valuable to many government agencies, including the Food and Drug Administration (FDA) for the purpose of overseeing the safety and effectiveness of prescription drugs and conducting postmarket surveillance, and the Agency for Healthcare Research and Quality (AHRQ) for the purpose of analyzing comparative clinical effectiveness. The Academy has commented often on the importance of these initiatives.

Although the FDA is responsible for evaluating not only a drug's efficacy but its safety as well, the reality is that the drug review process emphasizes "approval" so that patients are able to have access to new drugs as soon as possible. The process imposes limitations because of the comparatively limited timeframes and parameters of clinical trials and the relatively small population of subjects tested. Only after a drug has been on the market and available to a broader population can a determination be made as to whether a drug is effective in treating medical conditions and whether there are any safety problems associated with its use. The Part D prescription drug utilization data provides a large quantity of data and includes information on specific medications, dosages and patterns of use. Therefore, Medicare Part D prescription drug utilization data should be made available to the FDA for the purpose of postmarket surveillance of prescription medications.

The Academy supports research on the comparative clinical and cost effectiveness of prescription drugs. Such research is a fundamentally necessary component of any rational approach to determining the value and usefulness of prescription drugs. Currently, only limited authoritative research exists that distinguishes the effectiveness and safety profile offered by any particular drug as compared to other drugs in the same or similar treatment class. Physicians, pharmacists, other health professionals, patients and purchasers of health care need objective, easily-accessible evidence-based information regarding the comparative clinical and cost effectiveness of prescription drugs in order to make knowledgeable and informed decisions. Therefore, Medicare part D prescription drug utilization data should be made available to AHRQ or other agencies that may be conducting research in the area of comparative effectiveness.

The Academy is also supportive of CMS providing data to external researchers, such as those based in universities. As stated in the draft guidance, much of the research being conducted by external researchers is designed to address questions of clinical importance. Because it is important to protect the Medicare Part D prescription drug benefit data from inappropriate use, the Academy is supportive of the CMS requirement that each request would be evaluated to determine whether:

1. a legitimate research purpose is presented by a responsible party,

2. the minimum data needed to conduct the study will be released, and
3. the confidentiality of beneficiary information is protected.[1]

In the proposed rule, CMS has requested comments on whether it should consider additional regulatory limitations to ensure that proprietary plan data or confidential beneficiary data is not released. The Academy strongly urges CMS to add additional language to protect information related to the identity of the prescription drug plans (PDP) and Medicare Advantage plans (MA-PD) reporting the data.

If external researchers and other federal agencies are using data to address questions of clinical importance, including medication safety and comparative effectiveness, the identity of the PDP or MA-PD reporting the data is information which is not necessary. Researchers using the PDE data for inappropriate purposes could determine plan sponsor proprietary information such as pharmacy reimbursement rates and market share data for individual medications within specific plan benefits.

Therefore, the Academy recommends that a fourth limitation be added requiring that plan sponsor identifying information not be transmitted to external researchers. This limitation should be extended to federal agencies that are not responsible for overseeing decisions pertaining to accurate and correct payment or otherwise overseeing Medicare reimbursement under Part D.

As mentioned in the Limitations section, this proposed rule does not address uses already permitted under section 1860D-15 of the Medicare Modernization Act. This includes use by the Office of the Inspector General (OIG) or others conducting audits and evaluations necessary to "to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement under Part D, price variation studies, risk score refinement studies including the mandated geographic variations in price and utilization study, the reinsurance demonstration evaluation, or other such uses."

AMCP appreciates the opportunity to submit these comments on the Medicare Part D Data proposed rule. If you have any questions regarding our comments or require any additional information, please do not hesitate to contact me at (703) 683-8416 or at jcahill@amcp.org.

Sincerely,

Judith A. Cahill

Judith A. Cahill
Executive Director

[1] Federal Register, Vol. 71, No. 201, p. 61453.

**Submitter :** Dr. Calvin Knowlton **Date:** 12/18/2006

**Organization :** excelleRx

**Category :** Hospice

**Issue Areas/Comments**

**GENERAL**

GENERAL

see attachment

CMS-4119-P-73-Attach-1.PDF

CMS-4119-P-73-Attach-2.PDF

excelleRx
An Omnicare Company

1601 Cherry Street, Suite 1700
Philadelphia, PA 19102
Phone: 877.882.7822
Fax: 215.282.1586

***Passionate for the Appropriate Use of Medication***

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: Comments on the Proposed Rule, "Medicare Part D Data,"
CMS – 4119–P

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rule, published in the Federal Register on October 18, 2006, that would allow the Secretary to use Medicare Part D claims information currently collected for payment purposes for research, analysis, reporting and public health functions. We are pleased the Centers for Medicare and Medicaid Services (CMS) is addressing, through rulemaking, the restrictions of section 1860D-15, which limits the Department's use of Medicare D claims data for payment purposes only. Clearly, CMS and other government agencies need access to Medicare Part D Claims data for a variety of reporting, oversight, evaluation and research functions. CMS also recognizes the importance of making such data available to external researchers. However, we are concerned that the proposed rule may not go far enough to ensure that Medicare Part D claims data are available to other public and private entities who are involved in the provision, management and coordination of services to Part D Medicare beneficiaries.

Our comments are set forth below as follows: Section 1 provides background on our company and our approach to medication therapy management (MTM) for individuals with chronic illness. Section 2 explains how we utilize claims data for analytic and evaluative purposes and identifies obstacles we have encountered. Section 3 concludes with our recommendations to ensure that access to Medicare Part D claims data are not unduly restricted while ensuring appropriate safeguards.

Section I – excelleRx's Medication Therapy Management Program

excelleRx is a medication management services company that serves patient populations with significant medication needs including patients who are terminally ill (in hospice care), patients who suffer from chronic pain, recipients of organ transplants and community-dwelling frail elderly. We currently provide pharmacy services to more than 75,000 hospice patients per month and are subcontractors in two of the Medicare Health Support (MHS) pilot projects. We are also working to integrate medication therapy management into the long term care setting where medication-related problems (MRPs) remain a significant contributor to morbidity and mortality, notwithstanding significant government regulatory activity and mandatory monthly drug reviews by consultant

The excelleRx approach to medication therapy management is to combine cutting-edge technology with peer-reviewed, evidence-based, clinical practices to reduce MRPs for individual patients. MRPs

include, but are not limited to, untreated indications, adverse drug events (ADE), duplicate therapies and potentially inappropriate medications (PIM). MRPs, if classified as a disease, would represent the 5th leading cause of death in the United States (Lazarou, et al).

Unlike drug utilization review, which is often conducted retrospectively, we staff three telephone-based Medication Management Support Centers (MMSCs) with clinical pharmacists who intervene in real time (24-7) to ensure that the prescription choice, dose, and monitoring parameters are based on evidence and the clinical needs of the individual patient, not prescriber preference. Our pharmacists make recommendations based upon each patient's individual clinical profile and history, using evidence-based, Medication Use Guidelines. We then monitor patient outcomes to ensure that the medications are effective. All patient data are stored in a significant data repository (over 50 million patient days), which we de-identify and mine regularly to refine our protocols, conduct overall program evaluations, and carry out health services research both independently and in collaboration with academic and industry scientists. Finally, we operate on a fixed-cost reimbursement to align incentives with desired performance that lead to quality outcomes.

Program evaluations demonstrate that the excelleRx MTM program:

- Accurately detects potential medication related problems
- Effectively changes medication regimens via evidenced-based recommendations to the prescribing physician
- Controls symptoms, such as pain, within fewer days than national benchmark averages
- Improves the clinical competence of those healthcare professionals with whom we interact
- Decreases medical costs
- Improves quality and standardize pharmacy care

Section II - The Importance of Data

Data, including claims data, are critical to the success of our interventions for several reasons. First, we create an electronic medical record for each patient in our system. Payor claims data help to populate each patient's clinical record and validate patient reported information regarding medical history including current and past diagnoses and medications. Claims data, therefore, support critically important medication reconciliation, allowing us to create a single, comprehensive medication profile that unifies therapies prescribed by multiple physicians, across multiple time periods, and multiple settings. Second, claims data enable us to monitor each patient's adherence and compliance with medication regimens. Third. claims data are used by excelleRx researchers with both academic and industry colleagues in research that supports development and refinement of clinical decision supports tools and risk stratification methodologies. Finally, we use claims data to evaluate program effectiveness and calculate the effect of MTMP interventions on medical costs. However, as the following examples illustrate, we face a number of obstacles to obtaining Part D claims data that we simply do not face with respect to other claims data.

Example 1 - Providing Medication Therapy Management for Medicare Fee for Service Beneficiaries with Chronic Illness

The Medicare Health Support (MHS) Pilot program is a three-year program designed to evaluate disease management concepts for fee-for service Medicare beneficiaries with chronic conditions.

Specifically, the program targets the sickest of the frail elderly beneficiaries with a primary diagnosis of Congestive Heart Failure and/or Diabetes. Seven MHS programs are now operational and include approximately 140,000 beneficiaries in the intervention group. The first of these three-year programs began in the July 2005. excelleRx serves a subcontractor in two of these programs, providing medication therapy management services to enrolled beneficiaries as part of the overall intervention strategy to improve outcomes and reduce costs.

During the initial contract negotiations Medicare signaled early on that Part D data would be made available to the disease management vendors and payors who are contracted to provide services in the MHS program. Part D data are essential to the provision of care management services for two primary reasons:

- First, Part D data enable us to identify and correct discrepancies with the medication profile previously gathered from self-reported beneficiary data
- Second, Part D data enable us to monitor adherence to prescribed medications, leading to timely intervention and prevention of avoidable illness and cost

Both of these - creation of an accurate medication profile and adherence monitoring - contribute to increased patient safety, better outcomes and increased effectiveness in providing services.

After stating that Part D data would be made available in August 2006, CMS subsequently informed the MHS contractors that they would not be able to provide Part D data, even though MHS contractors already receive Medicare A and B claims data for these beneficiaries. In response, some of the vendors took steps to quantify the impact on the contracted medical cost savings which is targeted at five percent. Vendors concluded that the net result of not having access to timely and accurate Part D data is decreased effectiveness of the MHS programs - that is, higher costs and poorer quality. CMS subsequently changed its position, apparently concluding that because MHS organizations were under contract to CMS, there was no impediment to data sharing. Acknowledging- that MHS contractors need Medicare Part D claims data in order to provide the comprehensive care management that is intended under the pilot, CMS therefore informed Part D sponsors that they must provide drug claim data to MHS contractors for those beneficiaries who are enrolled in MHS organizations. See Medicare Part D Manual, Draft, Chapter 7 at 14-15 (December 1, 2006). Unfortunately, however, this approach means that rather than obtaining necessary data directly from CMS, every MSO contractor will have to identify and obtain data from *each* individual plan -increasing the likelihood of further delay as MSO contractors work through the process with each individual plan. Seventeen months into a pilot program, we still lack data that are essential to achieving improved health outcomes and cost savings.

Example 2 - Maintaining the Frail Elderly at Home.

In 2003-2004, prior to implementation of Medicare part D, excelleRx partnered with a community-based provider of long term care community diversion (LTCD) that operated under contract with Florida Department of Elder Affairs. Florida's Diversion Program provides community-based services to residents who are dually-eligible and medically qualified for Medicaid nursing home placement. Services provided include long-term care services, and Medicaid-covered medical services. excelleRx subcontracted to provide medication therapy management (MTM) services to the enrollees with the LTCD provider. To benchmark our actual pharmacy related costs relative to other pharmacy providers

in this program, excelleRx obtained clinical data from the state Medicaid agency, Agency for Health Care Administration. As a result of being able to analyze prescription claims data, we were able to understand how our performance compared to other providers serving this underprivileged, chronically ill, frail elderly population.

At the same time, one of our partners, Gold Standard Multimedia, initiated an e-prescribing program with the Agency. This program relied extensively on prescription claims data to ensure accurate prescription transmission, appropriate drug selection and fraud and abuse identification.

Both our benchmark experience and Gold Standard's successful e-prescribing initiative would not have been successful in today's environment because prescription drug claim data that were available to us through the Medicaid agency in 2003-2005, are no longer available under Medicare Part D. Although working in conjunction with a Medicaid certified community-based provider, neither we nor the community-based provider have any contractual relationship with Medicare. Thus, it is important that CMS' final rule clarify that a contractual relationship with CMS is not a prerequisite to entering into a data use agreement when the data are sought for care coordination or care management of Medicare beneficiaries.

Example 3 -Applying Medication Therapy Management in Long Term Care

excelleRx is currently involved in refining our MTM protocols to support improvements in medication therapy in long term care settings. Nursing home residents are particularly vulnerable to adverse drug events because of the number of medications they take, the number of co-morbid conditions with which they are coping, and physiologic changes associated with aging and chronic illness that impact their bodies' ability to use and excrete drugs and associated metabolites. Potentially inappropriate prescriptions in long term care result in a 33-78% increase in risk for hospitalizations and 31-87% increase in risk for death (Lau, et al, Arch. Intern Med., 1/2005). Faced with the challenges of Part D and managing to multiple formularies and plans, long term care facilities and long term care pharmacies seek assistance in assuring that residents are receiving appropriate medication therapy. Access to Medicare claims data not only is crucial to populating each resident's clinical profile, but it will also be crucial to tracking and documenting outcomes and cost savings.

Example 4 - Research that advances our understanding of effective interventions.

Another critical use of data is conducting research to evaluate our programs, validate our processes and advance our understanding of what constitutes effective medication use and medication therapy management. excelleRx has a research division staffed by doctoral level pharmacists and nurse scientists, medical writers, physician consultants and biostatistics consultants. While we often partner with university-based research centers, we also have the in-house resources and expertise to conduct independent research. For example, during the Florida LTCD project, we conducted a study to compare medication expenditures for enrollees with the LTCD Provider to the average medication costs for similar FL residents. We are also currently engaged in a study to evaluate the predictive validity of our clinical decision support tools, and to statistically "weight" the rules we use to classify chronically ill older adults into categories of risk for medication-related problems. These studies help refine our tools and advance our knowledge of effective medication therapy management, allowing us to bring new, more efficient strategies for MTM to the market and to disseminate findings related to MTM best

practice via publication in peer-reviewed journals. However, none of this research could be undertaken if we were unable to access data regarding medication utilization by Medicare beneficiaries.

Section III -Conclusion and Recommendations

According to the Preamble, the proposed regulation would make Medicare claims files available to external researchers on the same terms and conditions as applied to Medicare Parts A and B data today. Data would be disseminated under CMS' standard use agreement protocols with assurances that the data were requested for a legitimate *research* purpose, the minimum data set was being released and the confidentiality of beneficial information is protected. While we support this approach, CMS needs to recognize that Medicare claims files are currently sought and used to support an array of care management and care coordination interventions including disease management strategies and medication therapy management. Further, the entity seeking the data may not have any contractual relationship with CMS or with a Medicare Part D program but may in fact be contracted with the provider (which may, for example, be a Medicaid provider). As adoption of electronic health records expands and with the anticipated growth of e-prescribing, use of claims data to inform treatment decisions and to drive care management and monitoring will only continue to grow. Accordingly, CMS' rule on data sharing must recognize the use of claims data extends well beyond research into the actual provision and monitoring of care.

Again, thank you for the opportunity to comment on the proposed rule.

Sincerely,

Calvin H. Knowlton, PhD, MDiv, RPh

President and Chief Executive Officer

**Submitter :** Dr. Roger Evans **Date:** 12/18/2006

**Organization :** Independent Consultant

**Category :** Other Health Care Professional

**Issue Areas/Comments**

**Applicability**

Applicability

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Beneficiary Access of Part D Data**

Beneficiary Access of Part D Data

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**GENERAL**

GENERAL

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Information to be Collected**

Information to be Collected

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Limitations**

Limitations

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Purpose of CMS Collecting Information**

Purpose of CMS Collecting Information

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Sharing Data with Entities Outside of CMS**

Sharing Data with Entities Outside of CMS

I concur with the analysis, and endorse the recommendations set forth in a letter dated December 18, 2006 submitted by AcademyHealth and signed by W. David Helms, Ph.D.

**Submitter :** Mr. Jayson Slotnik **Date:** 12/18/2006

**Organization :** Biotechnology Industry Organization

**Category :** Association

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

CMS-4119-P-75-Attach-1.PDF

Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

December 18, 2006

**BY ELECTRONIC DELIVER**

Leslie Norwalk, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

**Re: CMS-4119-P (Medicare Program; Medicare Part D Data; Proposed Rule)**

Dear Administrator Norwalk:

The Biotechnology Industry Organization (BIO) appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Proposed Rule regarding collection of and access to claims data under Part D of the Medicare program (the "Proposed Rule").[1] BIO is the largest trade organization to serve and represent the biotechnology industry in the United States and around the globe. BIO represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in the United States.

BIO's members are strongly committed to increasing the body of quality evidence available to further the clinical decision making process. Our members invest millions of dollars each year on clinical studies, both before and after Food and Drug Administration (FDA) approval to produce high-quality clinical evidence to support appropriate medical decision-making. BIO is committed to ensuring appropriate beneficiary access to innovative biological therapies, and we look forward to the opportunity to

[1] 71 Fed. Reg. 61445 (October 18, 2006).

work with CMS to ensure that the collection and usage of Part D claims data furthers this access for all Medicare beneficiaries.

BIO continues to support a rigorous research process that encompasses all aspects of a disease, from examining how a disease affects the body to studying the costs and benefits of therapies. Our members' research initiatives advance the understanding of disease pathology and therapeutic mechanisms of action, clinical effectiveness in naturalistic settings, health-related quality of life, and health economic impacts of therapies, as well as clinical safety and efficacy. The development of evaluation of therapies is part of this broader research process and must be considered in context.

As we have noted in previous comment letters, such as our comments on the "Coverage with Evidence Development" (CED) policy, BIO's members are committed to the development of high-quality evidence about diseases and their treatments.[2] While we are uncertain about the statutory authority for the data usage CMS has proposed, we agree with CMS that the usage of the Part D information presently being collected could offer significant benefits to the public health, particularly in the area of pharmacosurveillance. The value and limitations of claims data, however, are also well known. While BIO commends the Secretary for considering expanded usage of Part D claims information, we are concerned that there is not enough information in the Proposed Rule about the procedures that will be put in place to account for limitations in the use of this information and to allow interested parties to provide input on specific uses, particularly those involving coverage and payment decisions. These substantial concerns underlie all of BIO's comments to the Proposed Rule.

The highlights of BIO's comments are as follows:

- The use of Part D claims information by the government to establish coverage and reimbursement policy raises a series of questions about the use of the data that are not answered in the Proposed Rule. Specifically, BIO urges CMS to recognize the limits of claims data and describe in detail the process it expects to use to solicit and consider public input on various uses of the data,

---

[2] See, for example, BIO Comment Letter to Steve Phurrough Re: "Guidance for Public, Industry, and CMS Staff: National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development" (September 22, 2006).

particularly with regard to studies designed to influence plan coverage and payment decisions;

- The Part D claims data should be available to researchers outside the federal government in much the same manner that claims data from Parts A and B are available currently. The capacity to use this data to enhance medical knowledge will be greatly enhanced by public access to Part D claims information, provided that access is available in an organized and transparent way.
- The definition of "commercial purposes" must be narrowly construed so that the integrity of the use of the data is not compromised but access to the information is not unduly hindered.

## I. Statutory Considerations

The proposed rule contains extensive commentary on the statutory authority that CMS proposes to exercise in using Part D claims information for a variety of purposes. CMS proposes to use the contracting authority provided under section 1857(e)(1) of the Social Security Act ("the Act"), incorporated into Medicare Part D by section 1860D-12(b)(3) of the Act as the basis for using the claims information for a variety of proposed purposes beyond the payment issues for which it was originally being collected, delineated in section 1860D-15.

BIO supports efforts to ensure that accurate and comprehensive information about health care is available to facilitate high quality research on appropriate treatments using biotechnology therapies. As we will discuss further in the balance of this letter, we are generally supportive of efforts to assure that all researchers have access to Part D claims information, which is a rich source of data regarding the role played by medicines in the health and well being of Medicare beneficiaries. However, we have not completed a review of all of the legal questions raised by the proposed rule and accordingly do not take a position on CMS' statutory authority.

The balance of our comments focus on the importance of careful use of the Part D claims information, but BIO asks that the agency, in its final rule on these issues, provide more guidance on how it interprets the various statutory provisions at issue here.

## II. The Value and Limitations of Claims Data

While the collection and development of Part D claims data has tremendous potential to further clinical knowledge and enhance clinical decision-making, BIO urges CMS to recognize the limitations of Part D claims data and to exercise extreme caution in using this data to establish coverage and reimbursement policy. Part D claims data alone provides only a very partial picture of a patient's health care and health outcomes. Even when used in conjunction with Part A and B claims data, this data has significant limitations and should not be used in isolation to establish coverage and reimbursement policy.

As CMS indicates in the Proposed Rule, the Part D data that the agency proposes to use for a variety of purposes were originally designed to assure accurate payment of Part D plans, reflecting "True Out of Pocket Costs" (TrOOP). While BIO agrees that the data could prove to be quite useful for a number of other purposes, the data elements available will not always be exactly on point for the questions that CMS and other agencies will be seeking to answer. Often the information will provide only surrogates for the actual information being sought. As indicated in the Proposed Rule, the usage of particular products, for instance, will only be suggestive of the presence of a particular diagnosis. While this will in some circumstances expand the diagnostic information as compared to what are currently available using Medicare claims, it also illustrates some of the limitations facing researchers using this claims data.

As a result of these limitations, working with claims data for the purposes that CMS has described—whether from existing Part A and B claims, or the proposed use of Part D information—will require substantial creativity. In some instances, the information provided by claims data will be all that is required, and research using only the information available on Part A, B and D claims may produce viable and highly interesting results. In many cases, however, this claims data will not give informative results, but rather indicate the need for additional research that would require data not available in Part A, B and D claims datasets.

Given the complexity of these issues, BIO believes that more information is needed for the public to evaluate the uses of Part D payment information that CMS has proposed. BIO believes that a more clearly delineated process is necessary before the proposed dataset can be used for many purposes, particularly those that may inform coverage and payment

decisions. In the Proposed Rule, CMS references a number of potential uses of the data that could have profound effects on coverage under either Parts D or B. However, CMS does not offer detail on the process that will be used to allow for public analysis of the results of any of the proposed research projects and input into any of the regulatory or legislative proposals that may result. BIO urges CMS to release more detailed information about the specific initiatives it has proposed and as well as more information about how the agency intends to approach these and other uses of the data given the limitations of the data in question. In addition, BIO urges CMS to allow for a process for outside analysts to review, comment on and critique the study methodology and the results of the research of CMS and other agencies using Part D claims data, along with a process for public input prior to the use of these data in legislative and regulatory proposals.

Particularly if the Part D claims information is to be used as the basis for coverage and payment decisions, a detailed framework describing the process by which these decisions will be made is required. This structure should detail:

- The evidentiary standards that will be used;
- The process for appeals from adverse decisions; and
- Assurances that the process will be fully transparent.

The Proposed Rule does not address these issues. BIO believes that if CMS is to move forward with its proposal to use Part D claims information, particularly as the basis for decisions related to coverage and payment, the agency has an obligation to develop and disclose procedural safeguards along these lines.

This process should include provisions for public comment on specific coverage and payment decisions—with adequate time for replication of the analyses on which these decisions are based—along with an appeals process that is open to manufacturers of products for which coverage is restricted or denied. The process should also include time for public meetings to provide detail on the analyses performed using Part D and other claims information that results in coverage and payment decisions, including the methodologies used, detailed findings and potential limitations of these findings.

The evidentiary burden for any effort to restrict coverage and payment on the basis of Part D claims information must lie with CMS, and

any such decisions should not be effective until the entire process, including appeals, is completed.

III. The Importance of Public Access to the Data

BIO agrees with CMS that the Part D data the agency proposes to collect could be extremely valuable to CMS and other federal agencies in their efforts to protect the public health and provide health care services to Medicare beneficiaries. This claims data also has the potential to benefit public health more broadly by furthering understanding of disease and treatment options, as well as for purposes such as pharmacosurveillance. We believe that this data, linked to currently available claims data from Medicare Parts A and B, could greatly enhance efforts to research and develop new drugs and biologicals and to improve the safe and effective use of existing products.

As an association, BIO has long believed that drugs and biologicals can be highly cost effective alternatives to other medical interventions, potentially reducing the need for surgical interventions and hospitalizations while offering significant improvements to quality of life. While our members have been able to produce evidence to support these contentions, the availability of Part D claims information would provide a rich new resource for researchers interested in these issues. In order for BIO and its members to conduct such research, as well as offer fully informed comments on any initiatives of CMS and other agencies based on data collected under this proposal, we must be able to independently analyze the data. Consequently, BIO urges CMS to ensure that the data it proposes to collect are available to the public in much the same manner that claims data from Parts A and B are available currently.

In order to facilitate analysis by outside researchers, BIO urges CMS to release a summary file parallel to the current Physician Supplier Procedure Summary Master file along with a 5% sample Standard Analytical File (SAF) that can be linked to encrypted identifiers on Part A and B claims, in addition to other releases that may be necessary to allow the public to be fully informed about and comment on any regulatory actions based on the proposed dataset. These claims should be drawn from the same 5% sample used for existing SAFs, even though some sampled beneficiaries will not be enrolled in standalone Prescription Drug Plans (PDPs). This will allow for a complete picture of the health care interventions needed for

sampled beneficiaries, creating the most detailed dataset available to date on the medical value of drug and biological therapies.

In constructing these files, we would urge CMS to include as many data elements from the Part D claims information as possible, without jeopardizing beneficiary privacy, to ensure research can control for as many confounding elements as possible. For example, detailed information about Part D plan formulary and tiering structures will be particularly useful in this regard.

CMS may also wish to consider constructing a mechanism to allow outside researchers to access Part D claims information for pharmacosurveillance purposes. Such a mechanism would require an investment of time and resources materially greater than a SAF release, but could generate significant improvements in the safe utilization of drugs and biologicals by expanding the pool of researchers attempting to identify and prevent potential adverse events.

In summary, BIO agrees with CMS that the data it proposes to collect could produce significant benefits for the public health, benefits that can be compounded by assuring that the data are available for public use that can improve the safety and effectiveness of current uses of drug and biologicals while also aiding in the development of further innovations.

## IV. Defining "Commercial Purposes"

In the Proposed Rule, CMS requested comments on whether it should consider additional restrictions to guard against "the potential misuse of data for non-research purposes, commercial purposes or to ensure that proprietary data or confidential beneficiary data is not released."[3] BIO believes that the current protections for claims data released under Parts A and B, through the use of a privacy board for claims data that are considered fully identifiable, and research protocols with data use agreements for Limited Data Set (LDS) releases provide adequate protection of beneficiary privacy. We assume that LDS releases of Part D claims information will remove or encrypt data elements in much the same way that the current SAF LDS files are constructed, effectively preventing the re-identification of individual beneficiaries. However, we would again urge the agency to

[3] 71 Fed. Reg. at 61453.

**Submitter :** Ms. Tracy Baroni Allmon **Date:** 12/18/2006

**Organization :** Caremark

**Category :** Health Plan or Association

**Issue Areas/Comments**

**Applicability**

Applicability

A. Information To Be Collected. CMS states that in order to avoid duplicative efforts, it will access the plan s claims data submitted pursuant to section 1860D-15, so that plans would not have to submit the claims information twice. It will therefore refer to accessing rather than collecting the data. By this language, CMS implicitly acknowledges that it lacks the authority under section 1860D-12 to require the submission of this data by Part D plans. The submission of identical data a second time is not only duplicative as a practical matter, but cannot under any circumstances legitimately be viewed as either necessary or appropriate, which is the only type of data CMS is authorized to collect under section 1860D-12.

Setting aside the semantics, CMS is proposing to use and disclose plan data collected pursuant to section 1860D-15 in a manner and for purposes strictly prohibited by that section.

Regarding the actual data elements that CMS proposes to collect or access for these broader purposes, CMS lists the entire PDE record of approximately 37 elements, including pricing data, cost data and plan identifiers. There is no question that this is highly valuable, proprietary plan data, the disclosure of which beyond CMS would undermine the integrity of the Part D bid process and ultimately result in higher drug costs. This is precisely why Congress determined that this information should be protected from the type of disclosure being proposed by CMS. Even if CMS were to successfully invoke section 1860D-12 to collect this data, this would not negate the protections in section 1860D-15, or the rationale behind them.

Recommendation: CMS may and does collect all the data elements listed in the proposed rule, but it may only do so subject to the restrictions imposed by section 1860D-15(d) and (f) of the MMA, and as implemented by 42 CFR 423.322(b) and as contractually agreed to by CMS in its contract with each Part D sponsor. If CMS wishes to use the data for broader purposes, it should approach Part D plan sponsors with its proposal and work in a collaborative manner with them to establish a mutually acceptable framework in which to do so. This may involve having the Part D plans undertake the data analyses in question if they are willing to do so.

**Beneficiary Access of Part D Data**

Beneficiary Access of Part D Data

B. Purposes of CMS Collecting Information. In proposed section 423.505(f)(3), CMS lists four broad purposes for which the Part D sponsors claims data will be used and disclosed. The first is public reporting of overall statistics associated with the Part D program. This purpose can be achieved without CMS having to use or disclose Part D sponsors claims data. CMS currently imposes detailed reporting requirements on Part D plans to provide CMS with a broad array of statistics, covering every aspect of the program and the plan s operations, including enrollment and disenrollment, various plan programs such as MTMP, grievances and appeals, exceptions and prior authorizations, drug price comparison data, generic dispensing rates, utilization review and quality assurance data, aggregate rebates, call center metrics and other customer service measures. Part D sponsors are also required to provide CMS with information on premiums, plan design, service areas, formularies, and networks, among other plan information which, together with the reporting information, provides an extremely comprehensive picture of the program, how enrollees are accessing it, and how well plans are performing. While this data will not necessarily allow CMS to do every type of analysis described by CMS in the proposed rule, it will certainly achieve the intended purposes in this section more than adequately. Beyond that, CMS is in no way prevented from partnering with one or more Part D sponsors to use their data, alone or in combination, to do additional studies and analyses.

The same holds true for the other purposes mentioned as well. CMS has more than sufficient data reported to it by Part D plans other than Part D sponsors claims data to make evaluations of the Part D program, support legislative proposals and demonstration projects. To the extent that CMS wishes to use the data for payment oversight or program integrity services, this is specifically permitted under section 1860D-15(d) and (f) and 42 CFR 423.322(b), and so no further authority to do so is required, provided that CMS limits its use of claims data to this purpose and does not disclose it to third parties or other government entities. Legislative proposals and demonstration projects do not require the disclosure of every claim and related payment information of every Part D sponsor, although plans may well be willing to provide data for these purposes (e.g. to determine the cost of moving coverage of some drugs from Part B to D or vice versa), or may themselves be willing to do these analyses on their own data and provide the results to CMS or to otherwise collaborate with CMS for these purposes.

Recommendation: Most of the purposes described by CMS in the regulatory proposal can be achieved with the very robust set of statistical data already provided by Part D sponsors. If CMS believes that it would be helpful to analyze claims data for some of these purposes, it can and should collaborate and partner with Part D plans to do so. But CMS does not have the authority to mandate the release of the data for these purposes or to override the restrictions on permitted disclosures contained in the more specific provision.

**GENERAL**

GENERAL

See Attachment

**Information to be Collected**

Information to be Collected

C. Sharing Data with Entities Outside of CMS. In addition to the purposes for which the data could be used by CMS, CMS also proposes to share the data with entities outside CMS in the interest of public health. This would include sharing it not only with entities such as NIH, FDA and AHRQ, but also with researchers for purposes of assessing outcomes, clinical effectiveness, and generally studying diseases and their treatments. In fact, the proposed regulatory language does not even specify the purposes for which the data may be shared with other entities, and simply states that the sharing must be done in accordance with applicable Federal law.

However, as previously discussed, applicable federal law is section 1860D-15 of the MMA, and that section specifically prohibits the sharing of this data beyond HHS and limits the purposes to those related to payment and oversight activities under Part D.

Many plans already voluntarily share data with agencies such as the FDA, NIH and AHRQ, and with external researchers at universities and think tanks to provide valuable analysis and reports on public health topics, including drug trends, usage and clinical effectiveness. This is their prerogative to do with their plan data, within the parameters of HIPAA so that beneficiary privacy is protected. It is not for CMS to effectively appropriate the data, irrespective of its proprietary value or content, and decide how it should be used and with whom it should be shared. A fundamental underpinning of a private sector model is that it is indeed private and that, subject to appropriate government oversight, the assets and returns from that endeavor remain in, and are controlled by, the private sector. While it is true that the Part D program receives considerable government subsidies and it is to ensure the accuracy and integrity of those subsidy payments that the government obtains the claims data in the first instance this does not convert Part D or Part D plans into a public enterprise. Indeed, the essence of the Part D program, and what sets it apart from Medicare Parts A and B, is that it is provided through private sector competition. Appropriating the data of Part D sponsors is no different in effect than appropriating their data systems, facilities and other property, and indeed, is considerably more damaging, given the proprietary nature of the data and its potential competitive impact on the Part D bid process.

Recommendation: CMS may not and should not share Part D sponsors claims data except as currently permitted by Section 1860D-15 of the MMA and 42 CFR 423.322. Specifically, CMS may not share the claims data with any person or entity other than officers, employees and contractors of the Department of Health and Human Services ( HHS ), and only for the purposes of, and to the extent necessary in, carrying out [Subpart G dealing with payment], including, but not limited to, determination of payments and payment-related oversight and program integrity activities.

**Limitations**

Limitations

D. Beneficiary Access to Part D Data. CMS requests comments on the proposed 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. Under the HIPAA Privacy Rule, beneficiaries currently already have the right to request access to, inspect and copy their medication history and other protected health information ( PHI ) records. We strongly support this right, as well as the current right of beneficiaries under the HIPAA Privacy Rule to request amendments to that record, obtain an accounting of certain disclosures of PHI, request confidential communications and restrictions on the use and disclosure of PHI. We are therefore puzzled by the need for detailed, individualized claims data by CMS to study this proposition. If CMS is suggesting the development of electronic health records as a new mechanism by which individuals can access their records independently in some manner, we believe that is a worthwhile endeavor and would be eager to work with CMS to develop such a system. However, we see no need for mandatory disclosure of plan claims data to CMS or other government agencies or external third parties for this purpose, and indeed, believe that this type of disclosure would be inappropriate and unnecessary, and not in the best interests of beneficiaries. While the goal is a laudable one, we believe that CMS will achieve far more in this area by proceeding in partnership with Part D plans and other payers, and the health care industry generally, to develop the infrastructure and standards for this to succeed, and without the need for access to, or dissemination of, individualized beneficiary claims data.

Recommendation: Under HIPAA, beneficiaries already have the right to access and inspect their medication records. To the extent CMS is proposing some type of centralized or independently accessible electronic health record, we believe it should work in collaboration with all payers and the health care industry in general to develop the infrastructure and standards for this to succeed, and should not need access to detailed and individualized beneficiary claims information to do so.

**Submitter :** **Ms. Tracy Baroni Allmon** **Date: 12/18/2006**

**Organization :** **Caremark**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

See attachment. When I tried to submit in the above spaces, my text was too long. I am re-attaching the entire set of comments from Caremark. Thank you.

CMS-4119-P-77-Attach-1.DOC

CAREMARK®
*It all starts with care®*

December 18, 2006

Department of Health and Human Services
Centers for Medicare and Medicaid Services
Baltimore, Maryland 21244-1850
Via e-mail: www.cms.hhs.gov/eRulemaking

**Re: Comments on Proposed Rule CMS-4119-P: Medicare Part D Data**

Dear Sir or Madam:

SilverScript Insurance Company, a national Part D Sponsor, and SilverScript, Inc., a Part D pharmacy benefit management company (PBM), both affiliates of Caremark Rx, Inc., a leading PBM company, appreciates the opportunity to provide comments on the proposed data rule.

SilverScript Insurance Company (SSIC) is one of only 10 national PDPs servicing the Part D market. We have united with distribution partners, including health plans and Medicare Supplement providers, in the sales of our products nationwide. We bring substantial prescription drug benefit management experience through operating our own PDP (SSIC) as well as through our affiliate SilverScript, Inc. (SSI), a PBM offering prescription drug management services to Part D plans. SSI supports over 30 of our health plan clients, which have a combined membership of 2 million lives in Medicare Advantage and PDP programs.

We have reviewed the draft rule provided by CMS, and our comments are below:

## I. Executive Summary

Unlike traditional Medicare, the Part D program is a market-based model under which private plans compete to offer the best drug benefit at the lowest price. In such a model, data about a plan's drug costs, drug pricing, and claims experience is highly valuable and proprietary information. At the same time, the Part D program is government-subsidized, and the federal government therefore has a legitimate interest in and duty to review plan data to ensure that government payments are properly made. Congress recognized and carefully balanced these competing interests in plan data in the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") by requiring Part D plans to disclose their detailed claims data to CMS, but at the same time requiring CMS to keep this data confidential and use it only for the payment oversight purposes for which it was disclosed,

The proposed rule seeks to overturn this careful balance by giving CMS the right to use and disclose a Part D plan's data for a wide range of purposes and to a wide range of potential recipients. From a legal perspective, this is appropriation of plan data is directly contrary not only to the intent and spirit of the MMA, but also to its specific and unambiguous provisions. CMS' reading of the statute to conclude otherwise is contrary to the plain meaning of the language and violates several basic rules of statutory construction.

Perhaps even more importantly, from a policy perspective, the proposed rule would undermine the competitive private sector model on which Part D is based by widely disseminating highly sensitive, competitive and proprietary data. As the Federal Trade Commission staff have repeatedly stated in letters and reports addressing pharmacy benefit managers and the services provided, disclosure of proprietary data undermines the bid process and competition generally, and will result in increased drug costs.

Our comments address several specific issues. 1) Data to be Collected: CMS may collect the data specified in the proposed rule, but may use and disclose it only as permitted by section 1860D-15(d) and (f) of the MMA. If CMS does not wish these restrictions to apply, it should limit its data collection to aggregate data that is not subject to these restrictions. Alternately, if CMS wishes to use claims level data for broader purposes than permitted it by the MMA, it should obtain the permission of Part D sponsors and/or work collaboratively with them to develop a mutually acceptable framework in which to do so, and subject to any HIPAA constraints. 2) Purposes for Data Collection: Many of the stated purposes for which Part D sponsors' claims data would be used and disclosed under the proposed rule could be achieved using aggregate data provided to CMS by Part D sponsors that is not subject to the restrictions in section 1860D-15 of the MMA. Should CMS determine that certain purposes can only be achieved with Part D sponsors' claims data, it should seek the permission and cooperation of Part D sponsors to use this data, subject to any HIPAA constraints. CMS does not have the authority to effectively appropriate Part D sponsors' claims data, no matter how worthy it believes the purposes to be. 3) Sharing Data Outside CMS: CMS does not have the authority to share Part D sponsors' claims data outside CMS, except to CMS contractors for CMS payment oversight purposes. Any further sharing would need to be with the cooperation and permission of the Part D sponsors' whose claims data is involved, and subject to any HIPAA constraints. 4) Beneficiary Access to Data: Beneficiaries already have the right to access and inspect their health records under the HIPAA Privacy Rule. There is no additional regulatory authority necessary to ensure that they have this right. Any efforts to establish a different type of personalized drug history record should not require additional regulatory authority, and should be made in collaboration with all payers and the health care industry in general, so as to develop the necessary infrastructure and standards.

**II. General Comments**

**A. The proposed rule seeks to upset the appropriate balance that Congress has struck between program data that should be available for general dissemination and proprietary data that should be protected and used by CMS only as required for payment purposes.** While we support the use of Medicare Part D data for Part D purposes and certain public health purposes, such as those described by CMS in the proposed rule, and share CMS' view that it provides a "wealth of information," we do not believe CMS has the authority under the Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") to take or use the data for these purposes.

As CMS notes, Part D is unlike Parts A and B in one fundamental respect -- it is "based on a private market model." As Congress recognized when passing the MMA, and CMS addressed when issuing the Part D regulation, we believe that this fundamental difference in the way Part D operates warrants a fundamentally different approach to the use and disclosure of Part D plans' claims data. In particular, we believe that the MMA and Part D rule as currently written have drawn the proper distinction between, on the one hand, various types of aggregate or general program data (such as enrollment, formulary, drug price comparisons, MTMP and quality assurance data) that is collected from Part D plans and used and disseminated for program oversight, evaluation and beneficiary education purposes and, on the other hand, detailed,

identifiable claim-by-claim data that is recognized and protected as proprietary, and its use restricted to only that necessary for CMS to perform its payment oversight role.

As discussed in more detail below, we believe the proposed rule departs radically and inappropriately from these previous approaches and, indeed, appears designed to strip away the protections previously established by Congress and CMS to protect proprietary plan claims data. This is neither necessary nor beneficial for the program or the public good. CMS already collects more than sufficient program data to perform its oversight role without having to undermine the private sector underpinnings of the program. The many worthwhile uses for the data described in the proposed rule can still occur, but should occur through a market mechanism that respects the proprietary nature of the data and allows plans to participate in determining what should be analyzed, by whom and how, instead of having this be dictated by CMS.

**B. The proposed rule undermines the private sector competitive model on which the Part D program is based.** In the private sector model on which Part D is based, CMS does not act as payer and insurer, but instead contracts with private entities that act as the payers and insurers for prescription drug benefits. As CMS explained in the preamble to the Part D Rule[1]: "The Part D benefit was established by the MMA as a market based model under which marketplace competition ensures that enrollees receive low prices for prescription drugs." It was in recognition of this competitive private-market model that Congress, in section 1860D-15(d) and (f) of the MMA and CMS in section 423.322(f) of the Part D regulation specifically limited the use and disclosure of data - provided by Part D plans to CMS - for payment purposes. Both Congress and CMS understood, and the Federal Trade Commission[2] has repeatedly confirmed, that competition is premised on the ability of private entities to protect their proprietary data. Without this protection, and given the widespread use of the data envisioned by CMS, it is inevitable that Part D competitors will be able to obtain and evaluate the Part D claims data of each other. This will undermine the integrity of the bid process, as competitors will be able to adjust their bids based on their knowledge of each other's data, with the result that bids will be higher and drug costs will increase for all. It is for this reason that CMS, in addition to affording certain data automatic protection under 42 CFR 423.322(f), also provided Part D plans an alternative avenue in 42 CFR 423.502(d) for protecting a broader category of data, namely, recognizing an exemption for Plan data under Exemption 4 of the Freedom of Information Act ("FOIA"). The requirements for this exemption are that: "(1) disclosure of the information is likely to impair the government's ability to obtain necessary information in the future; (2) disclosure of the information is likely to cause substantial harm to the competitive position of the submitter; or, (3) the records are considered valuable commodities in the marketplace which, once released through the FOIA, would result in a substantial loss of their market value."[3]

In establishing these protections, both Congress and CMS were well aware of the potential value of the Part D claims data from a program as well as public health perspective. Nevertheless, it was recognized that without these protections, there would be no private sector model Part D benefit as envisioned, since these protections are essential to ensure the integrity of the bid process, and hence, the continued viability of the competitive market-based model on which the Part D benefit is founded.

---

[1] 70 Fed. Reg. at 4294.

[2] See, for example, FTC Staff Letter to Assemblyman Greg Aghazarian, September 3, 2004, where the FTC Staff stated "Whenever competitors know the actual prices charged by other firms, tacit collusion – and thus higher prices – may be more likely."

[3] 70 Fed. Reg. at 4332.

The proposed rule does not contain any discussion at all of the data protections in the MMA and the Part D regulation, let alone attempt to balance the existing protections against the value of the uses and disclosures proposed by CMS. While CMS makes passing mention of the need to address plans' "legitimate concerns" about their proprietary data in soliciting comments on appropriate protections when sharing data with other agencies and external parties, the proposal does not recognize that Congress has already addressed these legitimate concerns by enacting the very protections that CMS, in the proposed rule, goes to great lengths to overturn. Should CMS wish to use the claims data for purposes beyond those permitted in the MMA, the proper approach would be for it to approach the Part D plan sponsors in a collaborative manner to determine if it is possible to agree to a mutually acceptable framework that includes appropriate safeguards through which this can be done.

**C. The proposed rule's technical bases for ignoring the restrictions in section 1860D-15(d) and (f) of the MMA are flawed.** Quite apart from its failure to address the policy reasons for and rationale behind the protections in the MMA that it seeks to ignore, CMS' argument for its authority to disclose Part D plans' claims data as proposed is specious. Even without considering the rules of statutory interpretation, an interpretation of a statutory provision that would effectively eliminate two other provisions of the same statute must raise concerns.

1. No Ambiguity or Conflict to be Resolved

Contrary to CMS' assertion, there is no "statutory ambiguity" at all. Sections 1860D-15(d) and (f) both require the disclosure by Part D plans of data determined by the Secretary to be "necessary" or "required" to carry out CMS' payment responsibilities, and both contain clear, simple and unambiguous language limiting the permitted uses and disclosures of that data by CMS. Section 1869D-12(b)(3) contains a much broader and less specific provision, authorizing CMS to include in its contract with Part D plans:

*such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate.*

Even without considering the limiting language in section 1860D-12(b)(3) (which authorizes the Secretary "except as otherwise provided") and section 1857(e) (which authorizes the Secretary to the extent "not inconsistent with this Part"), there is no conflict or ambiguity to resolve. First, all that section 1860D-12(b)(3) does is provide the Secretary with authority to impose "other" contractual requirements, including the collection of additional information he deems "necessary and appropriate." Nothing in that section directs or requires the Secretary to disclose the information collected under Section 1860D-12 in a manner contrary to the restrictions in Section 1860D-15, and so the Secretary can clearly implement Section 1860D-12 without violating or ignoring Section 1860D-15. To the extent that the data collected under Section 1860D-12 overlaps with or duplicates information collected under Section 1860D-15, the Secretary is limited in what he can do with that information – not under Section 1860D-12, but under Section 1860D-15, since that information is governed by two Sections, one of which is more limiting (Section 1860D-15), but not contrary to, the other.

2. Contrary to Rules of Statutory Interpretation

CMS' proposed interpretation of Section 1860D-12 would ignore or effectively read out of the MMA the limitations in Sections 1860D-15. To do so is to violate at least three basic principles of statutory construction: (i) to give effect to the intent of Congress, which in clear and unambiguous terms stated that this information should be protected from disclosure, in recognition of its proprietary nature in a private sector competitive business model; (ii) to read the statute as a

harmonious whole or so that it is internally consistent i.e. if a provision can be interpreted in a manner that either gives effect to, or otherwise ignores or renders redundant, another provision, it should be interpreted so as to give effect to the other provision; and (iii) the more specific provision trumps the more general. CMS' interpretation runs directly counter to all three of the above rules of statutory interpretation: (i) it fails to give effect to the intent of Congress in establishing the protections for proprietary data; (ii) it interprets Section 1860D-12 so as to eliminate or ignore Section 1860D-15(d)(2)(B) and (f)(2); and (iii) it interprets the more general and broader language in Section 1860D-12 to effectively overrule the more specific and narrower language in Section 1860D-15.

3. Authority Under One Section Does Not Negate Restriction under Another

CMS decides that the qualifying language in each of Section 1860D-12(b) and Section 1852(e) are not a "hindrance" to its interpretation, because the language in Section 1860D "on its face, restricts the use of the information only when such information is collected under the authority of that section. Thus, nothing in section 1860D-15 of the Act will conflict with or be inconsistent with claims information collected under the authority of section 1860D-12(b)(3)(D) of the Act." This is simply untrue. The protection afforded to data collected under Section 1860D-15 is not lost simply because CMS seeks to collect the same data under another provision that does not include protections. On the contrary, it means that the data is now subject to both provisions, and must comply with any requirements and limitations of both. Otherwise the two sections are indeed inconsistent, one allowing disclosure and the other not, of the identical information. CMS' quotation of language from the preamble that states that the limitations in Section 1860D-15 do not apply when the data is collected under "some other authority" is, at best, misleading, since CMS' quoted language fails to include the prior sentence in the preamble, which states the critical and distinguishing feature that would allow the limitations in Section 1860D-15 to be ignored, namely, that the data is being collected by "others with independent authority...using their own authority."[4] That is not the case here – there is no other entity acting with independent authority, but on the contrary, in both instances it would be CMS acting under the authority of the MMA. The fallacy in CMS' argument can perhaps best be demonstrated by a simple example. Say, for example, that a bank enters a contract with a security service to protect its premises. Section 1 of the contract authorizes the security service to enter various parts of the bank as needed to perform its services. Section 2 authorizes the security service to enter the vault, provided that the security service locks the door on its way out. According to CMS' interpretation, as long as the security service enters the vault under authority of section 1, rather than section 2, it is not required to lock the door behind it on the way out.

4. Qualifying Language Limits Secretary's Authority Under Section 1860D-12

Lest there be any doubt that Congress did not intend for the broad and unspecific authority granted in section 1860D-12 to trump the more specific and limiting language in other provisions, it included not one, but two, limiting phrases (i.e. "Except as otherwise provided" and "not inconsistent with"). These phrases serve to prevent the Secretary from collecting information in a manner that is "otherwise" to or "inconsistent" with the way in which that same information may be collected elsewhere in the MMA. Thus, Section 1860D-12(b), on its face, limits the Secretary's authority under that section to collecting only such information and only in such a manner as is consistent with and not otherwise to Section 1860D. Since section 1860D-15 specifically limits how Part D claims data may be used and prohibits its broad dissemination, the Secretary does not have the authority under Section 1860D-12 to undo those limitations or allow such broad dissemination as is proposed. Thus, the double limiting language in Section 1860D-12 and Section 1857(e) prevents even an implied conflict or inconsistency from occurring and

[4] 70 Fed. Reg. at 4399.

therefore, obviates the need to even apply the principles of statutory interpretation – by its terms, the authority granted in Section 1860D-12 stops where the limitations in Section 1860D-15 start.

**D. The alternate authority cited in the proposed rule for CMS to collect and disseminate Part D data does not extend to plans' claims data or for these broad purposes.** Putting aside the restrictions on use and disclosure of claims data in Section 1860D-15 and the limiting language in Sections 1860D-12 and 1857(e)(1), Section 1857(e) only allows the Secretary to include such "other" contractual provisions (including requiring information) as the Secretary finds "necessary and appropriate." Although broad and general, this authority is not without any parameters. There must be at least a prima facie showing that the additional contractual terms are indeed both "necessary" and "appropriate."

While Section 1857(e) does not specifically state for what the contractual provisions must be necessary and appropriate, since these are provisions in the contract between a Part D sponsor and CMS, the only reasonable interpretation of this language is that the provision must be necessary and appropriate for the implementation of Part D. This would be consistent with the introductory language in Section 1860D-12(b)(3), which states that the provisions of Section 1857 apply to Part D contracts in the same manner as they apply to MA organizations. In each case, the sections are dealing with contractual provisions to implement the MA and Part D programs respectively. CMS, however, proposes to interpret this provision as authorizing CMS to impose terms and collect information the Secretary determines is necessary and appropriate for him "to carry out his responsibilities as Secretary of the Department of Health and Human Services."[5] There is no basis for this broad interpretation, since both Section 1860D-12 and Section 1857 are found in Title XIII, which deals with Medicare, not Title VII, which deals with the duties and responsibilities of the Secretary generally. Absent some explicit language indicating that Congress intended to allow the Secretary to impose contractual terms on MA organizations and Part D plans for purposes that go well beyond the MA and Part D programs, it is overreaching in the extreme to read this basic contractual catch-all as authorizing the Secretary to impose data collection obligations for purposes that go beyond not only Part D or Medicare generally, but indeed, go beyond CMS' and even HHS' purposes to those of other government agencies and even external researchers, whether private or public.

Finally, looking simply at the plain meaning of the terms "necessary" and "appropriate," CMS makes a showing of neither in proposing the additional data collection contractual requirements pursuant to Section 1860D-12. Since CMS is already collecting the identical data pursuant to Section 1860D-15, it is not "necessary" to include yet another contractual provision to collect the same data. In addition, since the only reason for CMS to include this provision is to attempt to escape its obligations under Section 1860D-15, this can hardly be viewed as "appropriate." Thus, quite apart from the restrictions in Section 1860D-15, CMS lacks the authority to collect, use or disclose Part D claims data for the purposes other than directly related to its administration and oversight of the Part D program. While there may other worthy uses and disclosures of this data, these must be acted upon voluntarily by plans, which have the option, subject to any HIPAA constraints, to make their data available as they deem appropriate, and subject to whatever safeguards and limitations they deem necessary to protect the proprietary aspects of its information.

---

[5] 71 Fed. Reg. at 61447.

## III. Specific Comments

**A. Information To Be Collected.** CMS states that in order to avoid "duplicative efforts," it will access the plan's claims data submitted pursuant to section 1860D-15, so that plans "would not have to submit the claims information twice." It will therefore refer to "accessing" rather than "collecting" the data. By this language, CMS implicitly acknowledges that it lacks the authority under section 1860D-12 to require the submission of this data by Part D plans. The submission of identical data a second time is not only duplicative as a practical matter, but cannot under any circumstances legitimately be viewed as either "necessary or appropriate," which is the only type of data CMS is authorized to collect under section 1860D-12.

Setting aside the semantics, CMS is proposing to use and disclose plan data collected pursuant to section 1860D-15 in a manner and for purposes strictly prohibited by that section.

Regarding the actual data elements that CMS proposes to collect or access for these broader purposes, CMS lists the entire PDE record of approximately 37 elements, including pricing data, cost data and plan identifiers. There is no question that this is highly valuable, proprietary plan data, the disclosure of which beyond CMS would undermine the integrity of the Part D bid process and ultimately result in higher drug costs. This is precisely why Congress determined that this information should be protected from the type of disclosure being proposed by CMS. Even if CMS were to successfully invoke section 1860D-12 to collect this data, this would not negate the protections in section 1860D-15, or the rationale behind them.

**Recommendation: CMS may and does collect all the data elements listed in the proposed rule, but it may only do so subject to the restrictions imposed by section 1860D-15(d) and (f) of the MMA, and as implemented by 42 CFR 423.322(b) and as contractually agreed to by CMS in its contract with each Part D sponsor. If CMS wishes to use the data for broader purposes, it should approach Part D plan sponsors with its proposal and work in a collaborative manner with them to establish a mutually acceptable framework in which to do so. This may involve having the Part D plans undertake the data analyses in question if they are willing to do so.**

**B. Purposes of CMS Collecting Information.** In proposed section 423.505(f)(3), CMS lists four broad purposes for which the Part D sponsors' claims data will be used and disclosed. The first is public reporting of "overall statistics associated with the Part D program." This purpose can be achieved without CMS having to use or disclose Part D sponsors' claims data. CMS currently imposes detailed reporting requirements on Part D plans to provide CMS with a broad array of statistics, covering every aspect of the program and the plan's operations, including enrollment and disenrollment, various plan programs such as MTMP, grievances and appeals, exceptions and prior authorizations, drug price comparison data, generic dispensing rates, utilization review and quality assurance data, aggregate rebates, call center metrics and other customer service measures. Part D sponsors are also required to provide CMS with information on premiums, plan design, service areas, formularies, and networks, among other plan information which, together with the reporting information, provides an extremely comprehensive picture of the program, how enrollees are accessing it, and how well plans are performing. While this data will not necessarily allow CMS to do every type of analysis described by CMS in the proposed rule, it will certainly achieve the intended purposes in this section more than adequately. Beyond that, CMS is in no way prevented from partnering with one or more Part D sponsors to use their data, alone or in combination, to do additional studies and analyses.

The same holds true for the other purposes mentioned as well. CMS has more than sufficient data reported to it by Part D plans other than Part D sponsors' claims data to make evaluations of the Part D program, support legislative proposals and demonstration projects. To the extent that CMS wishes to use the data for payment oversight or program integrity services, this is specifically permitted under section 1860D-15(d) and (f) and 42 CFR 423.322(b), and so no further authority to do so is required, provided that CMS limits its use of claims data to this purpose and does not disclose it to third parties or other government entities. Legislative proposals and demonstration projects do not require the disclosure of every claim and related payment information of every Part D sponsor, although plans may well be willing to provide data for these purposes (e.g. to determine the cost of moving coverage of some drugs from Part B to D or vice versa), or may themselves be willing to do these analyses on their own data and provide the results to CMS or to otherwise collaborate with CMS for these purposes.

**Recommendation: Most of the purposes described by CMS in the regulatory proposal can be achieved with the very robust set of statistical data already provided by Part D sponsors. If CMS believes that it would be helpful to analyze claims data for some of these purposes, it can and should collaborate and partner with Part D plans to do so. But CMS does not have the authority to mandate the release of the data for these purposes or to override the restrictions on permitted disclosures contained in the more specific provision.**

**C. Sharing Data with Entities Outside of CMS.** In addition to the purposes for which the data could be used by CMS, CMS also proposes to share the data with entities outside CMS "in the interest of public health." This would include sharing it not only with entities such as NIH, FDA and AHRQ, but also with researchers for purposes of assessing outcomes, clinical effectiveness, and generally studying diseases and their treatments. In fact, the proposed regulatory language does not even specify the purposes for which the data may be shared with other entities, and simply states that the sharing must be done "in accordance with applicable Federal law."

However, as previously discussed, applicable federal law is section 1860D-15 of the MMA, and that section specifically prohibits the sharing of this data beyond HHS and limits the purposes to those related to payment and oversight activities under Part D.

Many plans already voluntarily share data with agencies such as the FDA, NIH and AHRQ, and with external researchers at universities and think tanks to provide valuable analysis and reports on public health topics, including drug trends, usage and clinical effectiveness. This is their prerogative to do with their plan data, within the parameters of HIPAA so that beneficiary privacy is protected. It is not for CMS to effectively appropriate the data, irrespective of its proprietary value or content, and decide how it should be used and with whom it should be shared. A fundamental underpinning of a private sector model is that it is indeed private and that, subject to appropriate government oversight, the assets and returns from that endeavor remain in, and are controlled by, the private sector. While it is true that the Part D program receives considerable government subsidies – and it is to ensure the accuracy and integrity of those subsidy payments that the government obtains the claims data in the first instance – this does not convert Part D or Part D plans into a public enterprise. Indeed, the essence of the Part D program, and what sets it apart from Medicare Parts A and B, is that it is provided through private sector competition. Appropriating the data of Part D sponsors is no different in effect than appropriating their data systems, facilities and other property, and indeed, is considerably more damaging, given the proprietary nature of the data and its potential competitive impact on the Part D bid process.

**Recommendation: CMS may not and should not share Part D sponsors' claims data except as currently permitted by Section 1860D-15 of the MMA and 42 CFR 423.322. Specifically, CMS may not share the claims data with any person or entity other than officers, employees and contractors of the Department of Health and Human Services ("HHS"), and "only for the purposes of, and to the extent necessary in, carrying out [Subpart G dealing with payment], including, but not limited to, determination of payments and payment-related oversight and program integrity activities."**

**D. Beneficiary Access to Part D Data.** CMS requests comments on the proposed 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. Under the HIPAA Privacy Rule, beneficiaries currently already have the right to request access to, inspect and copy their medication history and other protected health information ("PHI") records. We strongly support this right, as well as the current right of beneficiaries under the HIPAA Privacy Rule to request amendments to that record, obtain an accounting of certain disclosures of PHI, request confidential communications and restrictions on the use and disclosure of PHI. We are therefore puzzled by the need for detailed, individualized claims data by CMS to study this proposition. If CMS is suggesting the development of electronic health records as a new mechanism by which individuals can access their records independently in some manner, we believe that is a worthwhile endeavor and would be eager to work with CMS to develop such a system. However, we see no need for mandatory disclosure of plan claims data to CMS or other government agencies or external third parties for this purpose, and indeed, believe that this type of disclosure would be inappropriate and unnecessary, and not in the best interests of beneficiaries. While the goal is a laudable one, we believe that CMS will achieve far more in this area by proceeding in partnership with Part D plans and other payers, and the health care industry generally, to develop the infrastructure and standards for this to succeed, and without the need for access to, or dissemination of, individualized beneficiary claims data.

**Recommendation: Under HIPAA, beneficiaries already have the right to access and inspect their medication records. To the extent CMS is proposing some type of centralized or independently accessible electronic health record, we believe it should work in collaboration with all payers and the health care industry in general to develop the infrastructure and standards for this to succeed, and should not need access to detailed and individualized beneficiary claims information to do so.**

We appreciate the opportunity to provide these comments. If you have any questions or would like discuss our comments, please do not hesitate to contact me at 202-772-3501.

Sincerely,

Russell C. Ring
SVP, Government Relations

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

**Organization :** Ways & Means Subcommittee on Health

**Category :** Congressional

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Dr. David Shern **Date:** 12/18/2006

**Organization :** Mental Health America

**Category :** Consumer Group

**Issue Areas/Comments**

**GENERAL**

GENERAL

See Attachment

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

Please note: We did not receive the attachment that was cited in this comment. We are not able to receive attachments that have been prepared in excel or zip files. Also, the commenter must click the yellow "Attach File" button to forward the attachment.

Please direct your questions or comments to 1 800 743-3951.

**Submitter :** Dr. Friedrich Port **Date:** 12/18/2006

**Organization :** Arbor Research Collaborative for Health

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**Beneficiary Access of Part D Data**

Beneficiary Access of Part D Data

See attachment (4119P-comments-ArborResearch.doc).

**GENERAL**

GENERAL

See attachment (4119P-comments-ArborResearch.doc).

**Information to be Collected**

Information to be Collected

See attachment (4119P-comments-ArborResearch.doc).

CMS-4119-P-80-Attach-1.DOC

**Medicare Part D Data**
**Part D Ruling: 4119-P**
**Comments on proposed rule from the Arbor Research Collaborative for Health**

As a contractor for CMS engaged in several CMS projects related to the management of end-stage renal disease (ESRD), a condition that is associated with a high financial burden to both the patient and to the Medicare system, we welcome ruling 4119-P, which 1) outlines the importance of collecting Part D data, 2) proposes the accessibility of such data to external researchers, 3) and identifies important applications of linkage of Part D data to other existing Medicare prescription drug and claims databases.

In order to assure the health of the Medicare population, we believe that it is essential that an electronic data system for Part D data be made available in linkable format, with details of prescriptions by patient, time, and location. Without access to such data, HHS and its contractors will not be able to evaluate or address shortcomings in the current management of chronic diseases.

**Comment on "Purpose of CMS Collecting Information"**

For our team's experience conducting outcomes research in ESRD, the following are priority areas of study using the Part D claims data:

1. Evaluation of medication use in the ESRD population, including identifying whether drugs that are clearly indicated for certain comorbid conditions (e.g., prior myocardial infarction or diabetes) are being administered. This is an urgent area of study because of the exceedingly high hospitalization and mortality rates observed in this population. Adequate and appropriate outpatient preventive care with medical and pharmaceutical management of existing cardiovascular disease and diabetes could potentially minimize the unnecessary worsening of chronic comorbid conditions that lead to frequent hospitalizations.
2. Whether medication use and drug prescribing patterns should be incorporated as a clinical performance measure for the management of comorbid conditions in ESRD patients, for which there is sufficient evidence that a drug's use can lead to an improvement in clinical outcomes.
3. Studying the trade-off in cost and clinical outcomes between more comprehensive outpatient care with its associated increase in outpatient medication costs on the one hand, and hospitalization costs on the other. It should be determined whether a lower aggregate cost of care can result from increased outpatient management because of its substitution for emergency room visits and hospitalizations.

**Comment on "Sharing Data with Entities Outside of CMS"**

We strongly support CMS's efforts to unify Part D prescription drug data with its existing data sources. Our group routinely accesses CMS claims data, and has had the privilege of evaluating several demonstration projects for which access to CMS data and the ability to link it to other

sources has been invaluable; we expect the same to be true of access to Part D data. This access will be further strengthened by the government's plan to link Part D data to the data warehouse (the CMS 723 database) now in development.

Friedrich K. Port, MD, MS
*President, Arbor Research Collaborative for Health*
*Emeritus Professor of Medicine and Epidemiology, University of Michigan*

Sylvia P. B. Ramirez, MD, MPH, MBA
*Vice President for Global Research and Development, Arbor Research Collaborative for Health*

Robert A. Wolfe, PhD
*Vice President for Biostatistics, Arbor Research Collaborative for Health*
*Emeritus Professor of Biostatistics, University of Michigan*

Ann Arbor, Michigan
December 18, 2006

**Submitter :** Dr. Barry Saver **Date:** 12/18/2006

**Organization :** UMass Medical School

**Category :** Physician

**Issue Areas/Comments**

**Applicability**

Applicability

Medicare part D drug utilization and costs.

**Beneficiary Access of Part D Data**

Beneficiary Access of Part D Data

CMS is collecting the information and should be able to use it to maximize taxpayer benefit from the substantial expenditures it represents. Not to do so is a foolhardy waste of money and, potentially, even lives.

**GENERAL**

GENERAL

The potential exclusion of part D data from access and analysis makes no sense from a public policy or health point of view. We already spend far too much on health care and pay for many procedures whose benefits are unproven. But to prevent use data that could lead to safer, more effective, and/or more cost-effective medicine would be the height of idiocy and the triumph of corporate greed over the public good. There is no rational justification for failing to reverse this grievous mistake.

**Information to be Collected**

Information to be Collected

Outside researchers should be able to access part D utilization data as they are other Medicare data. Strict procedures are already in place to ensure the confidentiality of Medicare data released to outside researchers. CMS has limited internal resources for research and far more value will be derived from these data if outside researchers as well as CMS personnel are able to analyze these data. There is no justification for not doing so. The American people have a right to expect their tax dollars to be used judiciously and effectively, and not just be used to fund a blank check to Big Pharma.

**Sharing Data with Entities Outside of CMS**

Sharing Data with Entities Outside of CMS

None - the information should be treated just like any other Medicare utilization data.

**Submitter :** Dr. Stephen Crystal **Date:** 12/18/2006

**Organization :** Rutgers University

**Category :** Academic

**Issue Areas/Comments**

**GENERAL**

GENERAL

Attachment.

CMS-4119-P-82-Attach-1.DOC

*Institute for Health,*
*Health Care Policy,*
*and Aging Research*

Rutgers, The State University of New Jersey
30 College Avenue
New Brunswick, NJ 08901-1293
732-932-8579 (voice)
732-932-8592 (fax)
scrystal@rci.rutgers.edu (e-mail)

Stephen Crystal, Ph.D.
*Research Professor*
*Director, Center for*
*Health Services Research on*
*Pharmacotherapy, Chronic Disease*
*Management, and Outcomes*
*Associate Institute Director for*
*Health Services Research*

December 18, 2006

U.S. Department of Health and Human Services
Centers for Medicare and Medicaid Services
Attention: CMS-4119-P
PO Box 8017
Baltimore, MD 21244-8017
Re: CMS-4119-P (Comments on 42 CRF Part 23 "Medicare Program; Medicare Part D Data")
[Information to be collected][Sharing Data with Entities Outside CMS]

In response to CMS' request for comments on these regulations, I am pleased to write to thank the agency for promulgating these draft regulations and to express my strong support, and that of my colleagues at the Center for Health Services Research on Pharmacotherapy, Chronic Disease Management, and Outcomes, for their implementation.

From my perspective as a public health, health services and health policy researcher, the case is compelling that access to these data for research and analysis by CMS, other federal agencies, and their grantees is essential in order that CMS can effectively meet its responsibilities for administration of the Part D program. Indeed, inability to use the data for that purpose would adversely affect the ability to make well-informed policy and regulatory decisions in a program of this magnitude, such as decisions about the regulation of formulary decisions by plans, to name only one of a host of issues. For this reason, there is a compelling case that CMS should use its statutory authority to require plans to submit such information as the Secretary may find necessary and appropriate, by collecting, for use for program evaluation, evaluation of utilization and outcomes, and the other stated purposes, the same claims information now collected under the authority of section 1860D-12(b)(3)(D). Given the substantial public interests at stake; the potential impact of this information for beneficiary outcomes; the need for well-informed program management; and the substantial sums of public funds involved, this is indeed a necessary, responsible, and appropriate course.

I believe that CMS is entirely correct in stating, in the proposed rule, that "we do not believe that the Congress intended to restrict the Secretary when the Secretary otherwise has independent authority to collect identical information to that collected under section 1860D-15 of the Act." This opinion is based on my understanding of the legislative history and Congressional intent, as a scholar of health policy, and on the basis of my experience, during the development of the MMA, directing several projects related to prescription drug coverage policy and the potential impact of Part D policy choices, funded by the Commonwealth Fund, AARP and Kaiser Family Foundation. In this process, I had the opportunity to testify before the Senate Finance Committee on the Part D proposals and closely observe the process of legislative development. My sense of the legislative history is that Congress's general intent was clearly that CMS would carefully evaluate the program on an ongoing basis and conduct the kinds of analyses referred to by CMS in the draft regulation, which require utilization of claims data in the program for program evaluation, not simply for payment processing. For this reason, MMA appropriately provides a broad authorization to CMS to require such data from plans as it may deem necessary for effective management of the program.

In addition, in order that the benefits provided under Part D can be used by beneficiaries and clinicians in a safe, effective and cost-effective manner, it is vital that the potential of the data for research on safety, comparative effectiveness and cost-effectiveness be realized by bringing to bear the collective expertise of the academic research community on the complex analyses of use and outcomes that are needed. Therefore, I strongly support the regulations' provisions for release of data to non-federal researchers.

I strongly support the comments from AcademyHealth which are being submitted separately and which address a number of the questions framed in the draft regulation and request for comments. In the remainder of these comments, I would like to briefly address just a few points, related to CMS's request for comments on "whether we should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to assure that proprietary plan data or confidential beneficiary data is not released."

Overall, I believe that the existing data use agreement protocols have worked very well to address these concerns, and that it is appropriate to delegate the details of these issues to that process rather than undertake to address every possible contingency at the level of formal regulations, given the diversity of possible study designs and circumstances. These procedures have provided strong protection for confidentiality.

With respect to the issue of commercial purposes and industry sponsorship, a number of complex issues arise which, I believe, can be appropriately managed through the DUA process. If there is felt to be a need for a more specific statement as to the appropriate objectives for research conducted under such DUAs, CMS could consider language similar to that incorporated by Senators Grassley and Baucus in their proposed bill entitled "Medicare Data Access and Research Act", along the lines of:

"Data provided ... under this section shall be used solely for purposes of research on the safety, effectiveness, quality, disparities, and related aspects of health care for individuals entitled to [Medicare]...conducted for the purpose of developing and providing generalizable knowledge to inform the public health through scientific publication and other forms of public dissemination."

Similarly, if there is felt to be a need for a more specific statement of criteria for DUAs, language similar to that of the Grassley-Baucus bill could be considered, such as requiring that: the research center requesting data has well-documented experience, a record of scholarship on the topic of the proposed

study, and a likelihood of successful publication, as demonstrated by a prior record of relevant publication by key staff; that the center demonstrates the public health importance of the proposed study; that there be a commitment to place results of the proposed study in the public domain through publication; that the center make available to the public, without charge, any product or tool developed using the data provided; and that, if support from an interested commercial entity is involved, researchers who are independent of the interested entity have the right to independently and freely publish the scientific results of the study.

However, given the complexity of these issues and the variety of cases that may present themselves, I believe that it is appropriate to address these issues through the DUA process rather than through formal regulation. This process has worked well thus far to achieve these purposes.

Finally, I would like to provide some comments supporting the potential public health value of research by the scholarly research community, conducted with Part D data merged with other data sources. Importantly, I would note that linkage of Part D data with a variety of clinical, contextual and outcome data – going well beyond Medicare Part A and B data – is vital in order to achieve the potential of such research. This is particularly the case for research on outcomes of pharmacological therapies. Observational studies can be subject to a range of biases due to unmeasured clinical and other differences between users and non-users; to address these problems, linkage with clinical and other covariate data is essential. The National Cancer Institute's SEER-Medicare program is an exemplar for such research. In order to permit timely completion of linkages with various sources of external data, it is important to retain the potential for data use agreements that permit researchers to link Part D data with other data, under approved protocols, as is the case for other CMS data under current DUA procedures.

Medicare Part D data, when linked to other datasets, represent a vitally important opportunity to improve the public health of beneficiaries by improving the knowledge base on outcomes, safety, adherence, disparities, and other aspects of pharmacotherapy among the elderly and disabled. While randomized clinical trials are the gold standard for studies of pharmaceutical outcomes, such data are unavailable on a host of questions that are critically important to inform therapeutic decisionmaking by physicians and patients and improve safety and treatment outcomes. Even if there is a sharp increase in national investment in needed RCTs, it will never be possible to answer every important question about outcomes for every beneficiary subgroup, condition and drug (or combination of drugs), given a host of feasibility, economic, ethical, power, duration and other constraints on RCT implementation. The absence of needed RCT data is particularly marked with respect to the elderly and disabled population served by Medicare, because RCTs often exclude or underrepresent the elderly and/or individuals with complex comorbidities, which are typical of the Medicare population. Thus, even when RCT data exist on efficacy in selected, less clinically complex patient populations receiving care at selected sites, they may not generalize to provide information on effectiveness within the diverse Medicare population treated in the broad range of clinical settings where they receive their care.

With respect to medication safety, it is important to note that Phase III RCTs typically conducted by manufacturers as the basis for review and approval of new drug applications by FDA are typically not powered to detect adverse outcomes that are low-frequency but may be severe, or that result from long-term exposure to the drug. FDA maintains a reporting system through which clinicians can report adverse events that appear associated with the use of approved drugs, but the utility of this system is limited by low reporting rates, absence of a defined denominator, and the difficulty of making valid inferences from spontaneous, essentially anecdotal data.

Thus, in the last several years, we have seen several instances where FDA has had to impose black box warnings, or even request withdrawal of an approved drug, based on evidence that emerged after a drug was approved and marketed, often long after (in some cases, after a drug's entire period of patent protection had expired or was about to do so). Evidence of such risks was often difficult to obtain and in several cases emerged serendipitously and almost by accident rather than from any systematic monitoring process.

Prescription drug claims files by themselves lack the diagnostic, outcomes and other information to support the needed studies. When merged with other data, however, they can become a powerful tool for improving public health by building the knowledge base on outcomes, positive and negative. An important point I would note here is that to achieve the full potential of these data, it is essential for researchers to have the ability to link Part D data not only to Medicare Part A and B data, but also to other data on outcomes, context and clinical characteristics of beneficiaries. Key examples include: death and birth certificate files; nursing home MDS; home health care OASIS files; disease registries such as the SEER-Medicare dataset developed by the National Cancer Institute to study outcomes of cancer therapies; geographical data on characteristics and healthcare resources of communities; information on characteristics of providers (e.g., use of primary medical care versus specialty care); and Medicaid data on healthcare encounters and services not covered by Medicare. Such information is essential in order to provide accurate accounting for outcomes and to best address the many scientific pitfalls and potential threats to validity that emerge when one moves from experimental to observational studies, such as unobserved variable bias and confounding by indication or counterindication.

For these reasons, I would argue that it is vital that procedures for Part D data releases follow the model successfully used by CMS for DUAs for other CMS data, rather than following a more restrictive model. Specifically, in addition to arranging where possible for data matching to take place with CMS or a CMS contractor, I would argue that it is important that the option remain for researchers to link data to other sources, under a DUA for identifiable data, and then deidentify the data to create an analytic file. Whether or not direct identifiers are released, of course, the data need to be treated as potentially identifiable in any case, since the level of detail of dates, diagnoses, etc. necessary for meaningful research will render the datasets potentially identifiable.

There are a great many key examples of prior research linking drug and medical claims data to produce findings of great importance to public health. Many of these come from prior work linking Medicaid prescription drug claims to claims for other services and other datasets, such as vital statistics. Cooper et al used Medicaid data linked to vital records and hospitalization data to find that infants with only first-trimester exposure to ACE inhibitors had an increased risk of major congenital malformations as compared with infants who had no exposure to antihypertensive medications. Previously, such use had been thought safe. (Cooper W et al, Major congenital malformations after first-trimester exposure to ACE inhibitors." N Engl J Med 354(23): 2443-2451, 2006). For the elderly population, linkage with vital records will be important to examine the impact of treatments on the risk of death. For example, the FDA has issued a black box warning on potential increased death rates among elderly who receive atypical antipsychotics to treat behavioral symptoms of dementia, a widespread off-label use of these medications, but the magnitude of this effect, and whether it is a class effect or medication-specific has not been well characterized.

Other work with Medicaid claims data for prescription drugs also illustrates the potential for research with Medicare prescription drug claims data. One key area where this offers insight involves the use of prescription drug refill data to study adherence and consistent use of therapies. In the HIV area, for example, consistent use of antiretroviral regimens is critical to avoid treatment failure for the patient and

emergence of resistant virus in the population. As one example, work done by our group has examined use of protease inhibitors (PIs) and non-nucleoside reverse transcriptase inhibitors (NNRTIs) over time, identifying important disparities in initiation and continuation of treatments that warrant development of interventions to improve consistency of treatment use. We found that consistent longitudinal use is difficult for many patients. Persistence of use was lower for minority beneficiaries despite comparable coverage for pharmacy and other health services through Medicaid. Our findings suggested the need to examine nonfinancial barriers to appropriate use of highly active antiretroviral therapy, and to develop and test programmatic strategies for supporting patients in remaining on these regimens consistently. (Crystal, S., U. Sambamoorthi, et al. "Initiation and continuation of newer antiretroviral treatments among Medicaid recipients with AIDS." J Gen Intern Med 16(12): 850-9, 2001).

Similarly, our group has used information on filled prescriptions from the Medicare Current Beneficiary Survey, linked with Medicare claims and interview data as part of the MCBS design, to examine predictors and disparities of antidepressant use in the elderly. Our work showed the importance of prescription drug coverage in achieving treatment of diagnosed depression. Similarly, other groups have conducted important research with MCBS data on prescription drug use. However, due to inherent limitations on the MCBS sample size, time lag in processing interview data, and other constraints such as absence of information on fill dates, there are important constraints in the use of MCBS data to study prescription drug use and outcomes in the Medicare population. Use of the claims data will provide a far more powerful tool for such research.

We hope that these examples provide additional demonstration of the great public health importance of making Part D claims data available to researchers. We commend CMS for its issuance for comments of these important regulations and would like to indicate our strong support for their promulgation.

Sincerely,

Stephen Crystal, Ph.D.
Associate Institute Director for
Health Services Research
Director, Center for Pharmacotherapy,
Chronic Disease Management, and Outcomes
Research Professor and Chair, Division on Aging

**Submitter :** Dr. Josephine Briggs **Date:** 12/18/2006

**Organization :** HHMI

**Category :** Health Care Professional or Association

**Issue Areas/Comments**

**Applicability**

Applicability

One extremely effective program which has shared large sets of CMS data with the research community is the United States Rĕnal Data System (USRDS), run jointly by the NIH (NIDDK) and CMS. This program has established mechanisms to provide high quality research data sets and provide help in their utilization, to de-identify data, and to review data requests for appropriateness. A similar partnership model should be considered in developing programs for access to Part D data. The value of Part D data for all research purposes will be substantially increased if mechanisms can be developed to permit linking with Part A and Part B data.

**Beneficiary Access of Part D Data**

Beneficiary Access of Part D Data

The Part D data can have substantial value for assessment of the effectiveness of health promotion and disease prevention activities of various government agenices, such as the NIH and CDC. As one example, the NIH runs a program, the National Kidney Disease Eduation Program (NKDEP. A critical goal of that program is to increase utilization of converting enzyme inhibitors in patients with chronic kidney disease who are at high risk of progression to ESRD. This program has the potential of substantial Medicare savings since it could reduce the number of new cases of end stage renal disease by as much as 10 to 20%, and care of the end-stage renal disease patient is a major component of Medicare costs. However, it has proven difficult to determine the effectiveness of out-reach programs to increase ACE use without access to regional and national data on prescription patterns.

**GENERAL**

GENERAL

Part D data can be of enormous potential public health benefit. I participated in the development of Healthy People 2010. Progress toward many of the goals in Healthy People 2010 could be more effectively monitored with access to the kind of information that Part D data could provide. A major limitation in many areas considered for inclusion was the absence of sources of data about prescription drugs. Availability of this data would strengthen oversight of existing programs, and aid the government in development of future health promotion activities.

**Information to be Collected**

Information to be Collected

The Part D data can have substantial value for assessment of the effectiveness of health promotion and disease prevention activities of various government agenices, such as the NIH and CDC. As one example, the NIH runs a program, the National Kidney Disease Eduation Program (NKDEP. A critical goal of that program is to increase utilization of converting enzyme inhibitors in patients with chronic kidney disease who are at high risk of progression to ESRD. This program has the potential of substantial Medicare savings since it could reduce the number of new cases of end stage renal disease by as much as 10 to 20%, and care of the end-stage renal disease patient is a major component of Medicare costs. However, it has proven difficult to determine the effectiveness of out-reach programs to increase ACE use without access to regional and national data on prescription patterns.

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

**Organization :**

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

**Issue Areas/Comments**

**GENERAL**

GENERAL

Please see attached comments in letter dated December 18, 2006.

CMS-4119-P-84-Attach-1.PDF

Consumer-Purchaser
DISCLOSURE
PROJECT Improving Health Care Quality through Public Reporting of Performance

December 18, 2006

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave., SW
Washington, DC 20201

File Code: CMS-4119-P (Medicare Program: Medicare Part D Data)

Dear Ms. Norwalk:

Thank you for the opportunity to comment on the proposed rule concerning use of Medicare Part D data. The comments that follow address both the proposed use of Part D data for purposes of research, analysis, reporting and public health functions and our strong belief that it should be used for additional purposes. This prescription drug data provides crucial information that not only can inform researchers but also consumers and providers about care, care delivery, and health care performance. In particular, many indicators of physician performance require information on which drugs are used, for which patients, and when they are used. Medicare Part D data is key element in supplying this information.

With regards to comments on the proposed uses, we strongly support the utilizing of Part D claims data, in combination with Parts A and B claims data, for purposes of research, analysis, reporting and public health functions. Of course, it is imperative that safeguards are in place to protect the privacy and security of patients' health information.

Beyond the uses for which comments were solicited, we also urge the Centers for Medicare and Medicaid Services (CMS) to use the data for the public reporting of physician performance as a strategy to promote better quality of care and more effective use of resources. CMS has already shown leadership in this area by fostering the adoption of evidence-based physician performance measurement through the Physician Voluntary Reporting Program. Nonetheless, it is important to promote and foster increased transparency by having information on all providers so that consumers can make better informed decisions about their health care. Using the Part D claims data, in combination with Parts A and B claims data, is an opportunity to provide more information on physician performance while at the same time not burdening physicians with data collection.

In addition there should be a mechanism by which CMS data, inclusive of Parts A, B, and D, can be pooled with private sector data to enable better performance measurement and public reporting. Again, the pooling of this data should include appropriate safeguards to protect privacy and security of patients' health information.

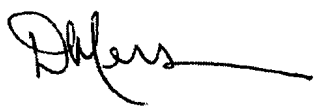
C/O National Partnership for Women & Families
1875 Connecticut Avenue, NW Suite 650
Washington, DC 20009

Generating valid performance information is a necessary prerequisite to changing the Medicare system to promote better value. What should shortly follow is changing the payment system to promote better quality and greater efficiency rather than quantity and errors, as the current system does.

Again, thank you for the opportunity to comment on these proposed rules. If you have any questions, please contact either of the Disclosure Project's co-chairs, Peter Lee, CEO of the Pacific Business Group on Health, or Debra Ness, President of the National Partnership for Women & Families.

Sincerely,

Peter V. Lee
Disclosure Project Co-Chair
Chief Executive Officer
Pacific Business Group on Health



Debra L. Ness
Disclosure Project Co-Chair
President
National Partnership for Women & Families