Submitter : Dr. Joan Warren **Date:** 12/18/2006

Organization : Dr. Joan Warren

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

I am writing to express strong support for making Medicare Part D data available for research purposes. As a nurse and an epidemiologist, I have had an opportunity to use Medicare claims for a range of studies. A major limitation of these studies is the lack of information about prescription drug use. The availability of prescription drug information, linked with other Medicare claims, would be a benefit to Medicare beneficiaries, the Medicare program, and society as a whole.

In the United States, the drug development process has limited post-marketing surveillance. Medicare Part D data in tandem with Part A and B could be used to assess the rate of complications and adverse events for persons using specific medications. Detecting these events could potentially result in the earlier detect of untoward events; with subsequent reduction in morbidity, mortality and costs. Part D data can also be used to identify patterns of care for persons with selected conditions and disparities in the pharmaceutical management of Medicare beneficiaries. In addition, these data could be used to develop comprehensive estimates of the cost of care for beneficiaries receiving selected medications.

In summary, these data have the potential to vastly expand the quality of care for Medicare beneficiaries and to assist CMS in understanding the treatment and costs of prescription drug care for the Medicare population.

Submitter : Mr. George Whitelaw **Date:** 12/18/2006

Organization : SMT, Inc.

Category : Private Industry

Issue Areas/Comments

GENERAL

GENERAL

SEE ATTACHMENT - WORD DOCUMENT

CMS-4119-P-86-Attach-1.DOC

SMT

DATE: December 18, 2006

TO: http://www.cms.hhs.gov/eRulemaking

FROM: George Whitelaw

RE: File Code CMS–4119–P
Comments on Proposed Rule, Medicare Program; Medicare Part D Data
Federal Register: October 18, 2006 (Vol. 71, No. 201, Page 61445-61455)

Introduction

We are writing in support of the CMS proposal to make Medicare Part D claims data available for research purposes and wish to emphasize the need to make sure that the available data is provided in such a way to be able to track patients across all segments of care (Medicare Parts A, B, C, and D, Medicaid, and SCHIP). As stated in the proposed rule, "the addition of outpatient prescription drug coverage to the Medicare program is the most significant change to the Medicare program since its inception in 1965" (p. 61446). The proposed expansion to allow evaluation of the outpatient prescription data will be crucial in order to do ongoing outcome and effectiveness evaluations. For example, Deep Vein Thrombosis (DVT) can occur in up to 50% patients after hip replacement surgery[i] without adequate thromboprophylaxis. It has been established that a significant financial burden falls on the Medicare program because DVT develops primarily in older age. However, after discharge from the hospital, a patient can enter a number of different sites of care (home, nursing home, etc.) and being able to examine the full treatment continuum will be critical in establishing accurate outcomes. It is apparent that actions in one part of the Medicare program could adversely impact outcomes and not be detectable without the ability to properly coordinate data. Post-operative prophylactic care, and subsequent health outcomes, is dependent upon appropriate drug management and availability. Structural and financial barriers, while intended to reduce prescription drug costs in Part D, may actually increase overall costs and decreased health outcomes by causing an increase of hospital readmission due to DVT or PE (Part A).

Understanding these and other critical issues will necessitate the provision of appropriate data across all parts of the Medicare program and external researchers being given the ability to follow individuals or classes of patients. This type of data will also allow for better identification of high-risk patients and determine if structural or financial elements are improving or hindering optimal care.

"Information to be Collected"

The 37 data elements proposed by CMS to be collected and disseminated are appropriate, however, we would like to emphasize that plan-specific parameters are also required in order to allow for proper evaluation of the impact of structure on the appropriate utilization of pharmaceuticals. Continuing our DVT example, if a patient upon discharge from surgery from the hospital is able to quickly fill a prescription for the appropriate medicine it is likely that

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incidence of DVT will be diminished. However, if there are certain plan features that hinder, delay, or reduce appropriate usage of prophylactics, one might expect to see an overall increase in DVT. Being able to make casual associations between structural plan elements and pharmaceutical usage will require that appropriate data elements are collected and disseminated. Knowing the level of co-payment relative to alternative therapies, plan level formularies, tier placement, and generic substitution policies, are just some elements that may be important to evaluation of overall performance of the Medicare program. Being able to easily associate plan level data with beneficiary prescriptions is important to determine what plan structures enhance care. Other critical data points that would enhance research findings would be the ability to determine how soon after discharge a patient was able to fill a prescription and refill rates. This data would need to be collected over all sites of care, e.g., discharge of a patient from the hospital to a nursing home and the care given in both sites.

"Purpose of CMS Collecting Information" and "Sharing of Information with Entities Outside of CMS"

We support the purpose for collection of information and believe that an accurate understanding of the interaction between different parts of Medicare, Medicaid, and SCHIP is currently lacking. We reiterate the necessity to "evaluate how the prescription drug benefits interacts with benefits provided under Parts A, B, and C, as well as Medicaid and the SCHIP program" (pg 61449). Disclosure to university-based researchers under the current data use agreement procedures will improve the economy, efficiency, and effectiveness of all components of the Medicare, Medicaid, and SCHIP programs. The ability of external researches to determine if pharmaceutical usage reduces overall spending or if unsafe or sub-optimal usage patterns are occurring will require the provision of "a complete picture of a beneficiary's care." This complete picture should also be comprehensive in that assessment of effective and efficient care should be permitted for all Medicare beneficiaries, not just the chronically ill. Identification of high-risk patients may require a more comprehensive evaluation. For example, research has indicated that only one in four patients dying of pulmonary embolism has had recent surgery,[ii] tracking of medical patients throughout the treatment continuum may potentially identify other risk factors for non-surgical patients. This could lead to significant savings for the Medicare program because DVT is one of the most common causes of preventable deaths among hospitalized patients[iii]. Being able to retrospectively track patients admitted for DVT through the different sites of care could be highly informative and help in assessment and creation of appropriate quality interventions that will impact health outcomes. Finally, we would like to support the notion of assuring proper data security, but do not believe that additional regulatory requirements, beyond the current existing data use agreement protocols, is unnecessary and would only diminish researchers ability to improving knowledge relevant to public health.

Finally, we applaud CMS for taking the initiative to allow Part D data to be utilized in order to examine the economic, efficient, and effective operation of the Medicare, Medicaid, and SCHIP programs. Inclusion of the Medicare Part D claims data will be crucial in order to make a comprehensive assessment of the functioning of all of these programs. Provision and assuring the coordination of the data will ultimately lead to significantly improved knowledge and increased efficiency of all parts of these programs.

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[i] Caprini, J.A et al., Economic Burden of Long-Term Complications of Deep Vein Thrombosis after Total Hip Replacement Surgery in the United States, *Value in Health*, 6(1) 2003

[ii] Thromboembolic Risk Factors (THRIFT) Consensus Group. Risk of prophylaxis for venous thromboembolism in hospital patients. BMJ, 1992: 305: 567-74

[iii] Agnelli G. Sonaglia F. Prevention of venous thromboembolism. Thrombosis Res 2002; 97(1): V49-V62

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Submitter : Mr. Walter Moore **Date:** 12/18/2006

Organization : Genentech, Inc.

Category : Drug Industry

Issue Areas/Comments

Applicability

Applicability

Please see attachment.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

Please see attachment.

GENERAL

GENERAL

Please see attachment.

Information to be Collected

Information to be Collected

Please see attachment.

Limitations

Limitations

Please see attachment.

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

Please see attachment.

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

Please see attachment.

CMS-4119-P-87-Attach-1.PDF

Genentech
IN BUSINESS FOR LIFE

Leslie Norwalk, JD
Acting Administrator, Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SE
Washington, DC 20201

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

Dear Acting Administrator Norwalk:

Genentech, Inc. ("Genentech") appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' ("CMS") Notice of Proposed Rulemaking ("NPRM") regarding the Medicare Program; Medicare Part D Data (the "Proposed Rule").[1]

As you are aware, Genentech is a leading biotechnology company focused on discovering, developing, manufacturing, and commercializing biotherapeutics that address serious unmet medical needs. Genentech has discovered and introduced over a dozen significant therapies for serious and life-threatening diseases, many of which affect the lives of Medicare beneficiaries, including cancer, heart disease, pulmonary disease, rheumatoid arthritis, and age-related macular degeneration.

The Proposed Rule sets forth CMS's statutory authority to collect Medicare Part D claims information ("claims data") for research, analysis, reporting and public health functions. In our view, CMS does not have express legal authority under the Social Security Act (the "SSA") to collect claims data for these purposes. Regardless, in the event CMS decides to proceed with finalizing the rule, we urge the Agency to address a number of issues that it omits from discussion in the Proposed Rule.

Our comments to the Proposed Rule fall into the following categories: (1) CMS' legal authority to collect claims data for the additional purposes set forth in the Proposed Rule; (2) issues we believe need more adequate discussion, including matters relating to data collection and maintenance, use of the claims data and the quality and reliability of the data collected; and (3) issues relating to patient privacy. These topics are discussed in more detail below.

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

A. COMMENTS RELATING TO "PURPOSE OF CMS COLLECTING INFORMATION"

1. CMS's Legal Authority

We disagree with CMS's interpretation of the SSA as it pertains to additional uses of claims data. At issue are two sections of the SSA pertaining to CMS's authority to collect claims data. The first section, section 1860D-15, relates specifically to Part D data collection for the purposes of making payment to Part D Prescription Drug Plans (PDPs) and Medicare Advantage Prescription Drug Plans (MA-PDs).[2] Sections 1860D-15(d)(2)(B) and (f)(2) limit CMS's authority to use claims data so that such data may only be used by "officers, employees, and contractors of the Department of Health and Human Services only for the purposes of and to the extent necessary in carrying out" section 1860D-15 of the SSA.

The other section discussed in the Proposed Rule, 1857(e)(1), pertains to information provided to the Secretary under Medicare Advantage.[3] This section provides that Medicare Advantage Plans must provide CMS with such information as the Secretary may find necessary and appropriate. CMS contends that the general authority to collect information found in section 1857(e)(1) is not only incorporated into Part D contracts through section 1860D-12(b)(3)(D) of the SSA but also trumps the restrictions imposed by sections 1860D-15(d)(2)(B) and (f)(2). Through this interpretation, CMS effectively nullifies, without Congressional assent, the restrictions contained in 1860D-15(d)(2)(B) and (f)(2).[4]

CMS correctly admits that section 1857(e)(1)'s broad authority directly conflicts with the restrictions set forth in 1860D-15(d)(2)(B) and (f)(2). CMS's interpretation of these sections of the SSA, however, seems to go against basic rules of statutory interpretation. Specifically, where two provisions are ambiguous or conflict, the more specific provision should trump the provision of general application. Here, sections 1860D-15(d)(2)(B) and (f)(2) deal directly with Part D data collection. On the other hand, section 1857(e)(1) was drafted for Medicare Advantage contracts and only became applicable to Part D contracts as a result of a statutory provision incorporating such provisions generally.[5] Accordingly, sections 1860D-15(d)(2)(B) and (f)(2), which were drafted specifically for Part D, should trump the conflicting provision set forth at 1857(e)(1).

We are concerned that CMS's interpretation renders the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA) restrictions virtually meaningless, which sets a dangerous regulatory precedent. If finalized as written, CMS could conceivably use this example when interpreting other sections of the SSA in ways that avoid legislative restrictions set forth in statute. As such, we request that CMS postpone finalizing the policies set forth in this Proposed Rule until its statutory authority is clarified or specifically endowed.

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2 SSA § 1860D-15(d)(2)(B) and (f)(2).
3 SSA at § 1857(e)(1).
4 71 Fed. Reg. at 61446.
5 SSA at § 1860D-12(b)(3)(D).

B. ITEMS NOT ADEQUATELY DISCUSSED IN THE PROPOSED RULE

Assuming CMS decides to proceed with rulemaking, we believe there are a number of issues that were insufficiently addressed in the Proposed Rule, and others that require additional clarification.

First, there are numerous issues surrounding the data collection process and maintenance of the data which need to be resolved. Second, there are a number of unanswered questions involving the use of claims data and the extent to which CMS will solicit and incorporate public input into such uses. Finally, there are specific issues relating to the value and reliability of claims data and whether such data may be used for commercial purposes.

The above concerns are magnified because the Proposed Rule clearly allows CMS to use these claims data to make coverage and payment determinations for drugs and biologics. Given this possibility, we urge CMS to resolve the issues set forth below before publishing a final rule on Part D data collection.

1. Data Collection and Maintenance Issues (Comments Relating to "Information to be Collected/Purpose of CMS Collecting Information")

The Proposed Rule provides that CMS will collect or access 37 data elements currently submitted under 1860D-15 of the SSA.[6] The Proposed Rule does not, however, provide any detail regarding the actual collection process or the maintenance of the raw data once collected. Specifically, CMS does not discuss the following about the Part D claims database, particularly when linked to Part A and B claims:

- Who will collect, link, and store the data? Who will be responsible for assuring that these databases are properly linked? Will it be CMS or a third party? (To the extent that third parties are involved, CMS should elaborate on how it will oversee third party contractors so as to ensure that patient privacy is not compromised.).
- Does CMS have an implementation plan that addresses the expected timeframe for data collection or analyses of such data?
- In what format will the data be stored and delivered to users?
- How will CMS determine whether the data collected are complete and accurate?
- Does CMS intend to limit who can access the data? Will the availability of the Part D data be similar to that currently in place for Part A and B data?

Not only are these issues not addressed, it also is unclear what opportunities there will be for public comment on these issues. We recommend CMS obtain public input on these issues and then publish a second Proposed Rule to obtain further comment before finalizing the current proposed rulemaking. Furthermore, to the extent Part D claims data will be available to the

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[6] 71 Fed. Reg. at 61447.

public, we recommend that CMS release a summary file similar to the current Physician Supplier Procedure Summary Master file along with a 5% sample Standard Analytical File 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 informed fully regarding any regulatory action that is grounded in a dataset.

2. **Data Use Issues (Comments Relating to "Purpose of CMS Collecting Information")**

In addition to our concerns relating to data collection and maintenance describe above, we also are concerned regarding the entities that will have access to the data and how the data will be used. Our concerns are heightened by the possibility that CMS may use these data for payment and coverage determinations.

Most importantly, the Proposed Rule is silent on whether the public will be given an opportunity to comment on or participate in choosing what studies using Part D claims data will be performed, the purpose of those studies, how they will be designed, how the data will be interpreted, and how the results will be used. Since these decisions will affect the rights of the public (including beneficiaries), especially if they are used to make payment and coverage decisions, we request CMS to elaborate on whether it will incorporate public comment into its use of the data. We further request that CMS publish a second draft of this rule for public comment, which claries the answers to the following issues:

- Other than CMS, which government agencies will have access to the data? Will CMS establish criteria which must be satisfied by federal or state agencies in order to qualify them to obtain and study the data?

- Which entities will determine which studies will be performed? For instance, will the Food and Drug Administration (the "FDA") determine the FDA studies?

- What non-government entities will be allowed access to the data? Will CMS use the same criteria currently established for use of Part A and B claims data?

- How will CMS determine what studies it will perform (and for what purposes) using Part D claims data? Will CMS need to pre-approve study requests from other government agencies? Will there be any opportunity for public input or comment into these decisions?

- Will CMS establish any criteria for study design that will minimize the potential for claims data to be used in studies where claims data likely will provide misleading or incorrect results? Will there be criteria that CMS will use to ensure the data are appropriately set up and analyzed? If so, will CMS discuss these criteria in subsequent rulemaking and provide opportunity for public comment? Will there be an opportunity for public comment or participation concerning the design of federal or state studies using Part D claims data?

- Will the public have an opportunity to review or analyze the results of these studies

before they are finalized or published?

- Will the public have an opportunity to comment on or otherwise participate in determining how CMS (or other agencies) will use the results of these studies?

- Will the public have an opportunity to duplicate CMS's research or conduct its own studies using the same data?

- Will there be a system in place to ensure that other agencies use the data appropriately and within established legal authorities?

- Will CMS use claims data (either alone or linked to Part A and B claims data) to compare the cost, safety, and/or efficacy of drugs or biologics? If so, will CMS provide an opportunity for public comment and participation in the design and implementation of these studies? Will the public have access to the raw data used during the trials to verify the results? Will the public have an opportunity to discuss or dispute the results of such trials before they are published?

- Will public and non-governmental stakeholders be able to partner with CMS or other agencies to perform studies using the claims data? Similarly, will CMS conduct pilot studies using claims data in which stakeholders can participate?

- Will CMS perform its own studies or will it contract with outside contractors to study the claims data?

Again, we recommend that CMS public input on these issues and then publish a second Proposed Rule to obtain further comment before finalizing the current proposed rulemaking.

3. Use of Data for Commercial Purposes (Comments Relating to "Sharing Data With Entities Outside of CMS")

We share CMS's concerns regarding the "potential misuse of the data for non-research purposes, commercial purposes or to ensure that proprietary data or confidential beneficiary data is not released."[7] We also appreciate CMS's concern for ensuring that patient privacy is protected. On the other hand, there are a wide range of legitimate uses under which a company like Genentech could study the claims data. As such, CMS should ensure claims data that are released do not include data elements that will allow an entity to identify a beneficiary. Provided that these protections are maintained, CMS should release as many data elements as possible.

C. QUALITY OF DATA (COMMENTS RELATING TO "INFORMATION TO BE COLLECTED")

The Proposed Rule raises several concerns regarding the value of the data collected. Specifically, CMS will collect the same claims information collected pursuant to 1860D-15 of the SSA, which are limited to 37 data elements chosen specifically to assist in making proper

[7] 71 Fed. Reg. at 61453.

payment to PDP's and MA-PD's. Absent from the 37 data elements is any mention of patient diagnosis. We fail to understand how the data collected can be useful from a clinical perspective without collecting information regarding patient diagnosis. We fear that, even if Part D claims data are linked to Part A and B claims data, not including the diagnosis for which Part D medications were prescribed will make it impossible to establish, among other things, why medications were prescribed, why they were discontinued, the cause(s) of any adverse events, and the safety and efficacy of medications in different populations. The inability to draw conclusions on such important clinical issues could undermine the utility of Part D claims data and limit their use.

In addition, it has been well established in the health services research literature that it is very difficult to draw conclusions about clinical outcomes, decisions, or events using claims data (even with patient diagnosis) in the absence of medical records to validate clinical issues. To the extent that CMS is, or might, consider using claims data to make clinically important payment and coverage decisions (for example, denying coverage for a drug or biologic or making a least costly alternative determination), it should explicitly acknowledge and discuss these limitations as well as obtain public comment on this issue before its final rulemaking on Part D data collection and before performing such studies.

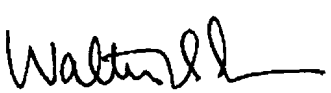
As such, we request that CMS address specifically whether it will require submission of patient diagnosis in addition to the 37 data elements that it currently collects before it uses claims data to study any clinical issues concerning Part D medications. Moreover, CMS should explicitly acknowledge and discuss the limitations of claims data when used to study clinical issues in subsequent rulemaking concerning Part D data collection.

D. CONCLUSION

For the reason stated above, we disagree that CMS has the authority to simply waive the restrictions set forth in section 1860D-15. Notwithstanding, if CMS decides to finalize the Proposed Rule, given the numerous unaddressed and unresolved issues set forth above, we request that CMS publish a second round of proposed rulemaking in response to the many questions raised to provide additional and appropriate opportunity for public comment prior to issuing a Final Rule.

Genentech thanks you in advance for your consideration of this request. Please do not hesitate to contact us with questions or for additional information.

Sincerely,



Walter K. Moore
Vice President, Government Affairs

Submitter : Mr. John Carlsen **Date:** 12/18/2006

Organization : Covance Market Access Services Inc.

Category : Drug Industry

Issue Areas/Comments

Information to be Collected

Information to be Collected

The attached Word file contains Covance Market Access Services Inc.'s comments on Sharing Data with Entities Outside of CMS (Proposed 423.505(f)(5)). If you have any questions, please contact me at 240/632-3548 or john.carlsen@covance.com. Our recommendations, which we discuss in detail in our attached comments, are the following:

? Recommendation 1: We recommend that the Chronic Conditions Data Warehouse (CCW) and other Part D-related claims data released by CMS be made available in LDS versions to allow for equal access to Part A, B, and D information.

? Recommendation 2: We recommend that CMS not impose additional regulatory limitations for external researchers beyond CMS s existing Data Use Agreement (DUA) protocols.

? Recommendation 3: We recommend that LDS versions of the CCW and other Part D-related claims data be consistent with other CMS LDS files.

CMS-4119-P-88-Attach-1.DOC

COVANCE
THE DEVELOPMENT SERVICES COMPANY

Covance Market Access Services
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December 21, 2006

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS–4119–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: **Comments on Medicare Program; Medicare Part D Data [CMS-4119-P]; Sharing Data With Entities Outside of CMS**

Dear Sir or Madam:

Covance Market Access Services Inc. (Covance) appreciates the opportunity to respond to the Centers for Medicare and Medicaid Services' (CMS's) proposed rule entitled "Medicare Program; Medicare Part D Data" (Proposed Rule). We are specifically addressing provisions of the Proposed Rule regarding the sharing of data with entities outside of CMS (Proposed § 423.505(f)(5)).

Covance is a research and consulting firm with over 17 years of experience in global reimbursement policy and health economics. We examine issues related to reimbursement policy and patient access to health care, and have continually monitored public and private health insurance policies and their effects on access to medical technologies.

Covance uses CMS's public use files and Limited Data Sets (LDS) to better understand the structure, processes, and outcomes of health care for Medicare beneficiaries with high-cost and/or high-volume conditions. We also seek to understand the clinical and economic value of the various health care interventions used for these populations. The results of these studies are used for activities such as designing prospective clinical trials, conducting general health services research, and providing comment on Medicare policies, programs, and payment systems.

Covance has three recommendations regarding the sharing of data with entities outside of CMS:

- **Recommendation 1:** We recommend that the Chronic Conditions Data Warehouse (CCW) and other Part D-related claims data released by CMS be made available in LDS versions to allow for equal access to Part A, B, and D information.

- **Recommendation 2:** We recommend that CMS not impose additional regulatory limitations for external researchers beyond CMS's existing Data Use Agreement (DUA) protocols.

- **Recommendation 3:** We recommend that LDS versions of the CCW and other Part D-related claims data be consistent with other CMS LDS files.

We discuss the relevant provisions of the proposed rule and our recommendations in detail below.

Recommendation 1: Covance recommends that the CCW and other Part D-related claims data released by CMS be made available in LDS versions to allow for equal access to Part A, B, and D information.

The Proposed Rule indicates that CMS plans to make Part D claims data available to external researchers through the CCW:

> *We will implement section 723 of the MMA by populating a chronic care condition data warehouse (CCW) which would be accessible by private researchers in order for such researchers to conduct studies related to improving quality and reducing costs of care for chronically ill Medicare beneficiaries. The CCW will include a beneficiary sample and will include Part D claims, in order to allow researchers to analyze prescription drug information. In this way, researchers would be able to receive a complete picture of a beneficiary's care, and determine whether the treatment of chronically ill beneficiaries (including Parts A, B and D treatment) is as effective and efficient as possible.*[1]

The CCW has been designated as a research identifiable file (RIF). RIFs consist of "data containing beneficiary or physician level information that either directly or indirectly identifies an individual."[2] CMS employs stringent data-use criteria that significantly limit the types of entities to which CMS will release RIF data. As a commercial entity whose work frequently is funded by pharmaceutical manufacturers, Covance would not have access to the CCW in its current format.[3]

The Proposed Rule states that in addition to releasing Part D claims data through the CCW, CMS plans "to make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality."[4] Although this proposed provision does not specify the format in which such data would be released, the inclusion of a link to the Agreement for Use of Centers for Medicare and Medicaid Services Data Containing Individual Specific Information—which applies to CMS data containing individual identifiers—suggests that CMS may be considering releasing this data as a RIF.

Many of the Medicare Part A and B data sets currently available as RIFs—including the Standard Analytical Files (SAFs), the Medicare Provider and Analysis Review File (MedPAR) File, and the Hospital Outpatient Prospective Payment System (OPPS) File—also are offered in LDS versions. LDS files contain beneficiary-level health information but, in contrast to RIFs, exclude specified

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[1] 71 Federal Register 61452

[2] CMS Type of Data: Identifiable Data. Available at: http://www.cms.hhs.gov/PrivProtectedData/09_IdentifiableData.asp. Accessed on December 18, 2006.

[3] CMS's Criteria for Review of Requests for CMS Research Identifiable Data state: "CMS has historically denied data requests from requestors wanting to evaluate the impact of prescription drugs if a pharmaceutical company finances the study." Available at: http://www.cms.hhs.gov/PrivProtectedData/02_Criteria.asp#TopOfPage. Accessed December 18, 2006.

[4] 71 Federal Register 61453.

direct identifiers as outlined in the Privacy Rule. Access to LDS data is governed by the following criteria:

> *To qualify for LDS, the data requestor must show their proposed use of the data meets the disclosure provisions for research purposes as defined in both the Privacy Rule and the Privacy Act. The research purpose must relate to projects that could ultimately improve the care provided to Medicare patients and policies that govern care. This includes projects related to improving the quality of life for Medicare beneficiaries or improving the administration of the Medicare program, including payment related projects and the creation of analytical reports.*[5]

Covance meets the above criteria and has been a longstanding subscriber to the CMS LDS files. We have used Medicare Part A and B claims data from these files to undertake epidemiological and economic profiling of many high-cost and high-volume cases, including cases involving chronically ill Medicare beneficiaries. We frequently work with our clients to develop comments on Medicare proposed rules and have used the results of our LDS analyses to demonstrate the need for improved reimbursement rates or revised payment policies. On multiple occasions, the data referenced in these comments have been a factor in CMS decisions that have resulted in more appropriate reimbursement and improved beneficiary access to important therapies. For example, a pharmaceutical manufacturer used the results of Covance's analysis of OPPS claims data to make a compelling case for CMS to include multiple line items when determining whether drugs meet the high-cost threshold for separate hospital outpatient payment (CMS's original methodology took into account only a single line item and understated the costs of certain drugs), prompting CMS to change the status of a cardiac drug from packaged to separately payable under OPPS. Covance also has played a crucial role in performing MedPAR data analyses in support of diagnosis-related group (DRG) changes that provided more appropriate inpatient reimbursement for certain cancer cases, helping to ensure continued beneficiary access for these vulnerable populations.

Although our analyses of Medicare Part A and B claims data have contributed to positive changes for Medicare beneficiaries, the lack of linkable Part D data often results in notable gaps in these analyses. For example, since we currently cannot identify prescribing patterns for drugs obtained through the retail or mailorder pharmacy, we are unable to estimate the effects of these drug regimens on the utilization of Part A and B services or health outcomes for Medicare beneficiaries.

It is imperative that CMS provide LDS versions of the CCW, Part D claims data linked to other Medicare claims files, and any other Part D-related claims data that may be released in the future. Offering such LDS files will ensure that all prospective users of Part D-related claims data have equal access to the data, so that meaningful analyses can be conducted to profile the complete picture of care for Medicare beneficiaries. The availability of these LDS files also will allow stakeholders to duplicate and validate studies conducted by academic institutions, federal agencies, and other entities that have access to RIFs for their research initiatives.

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[5] CMS Type of Data: LDS Policy. Available at: http://www.cms.hhs.gov/PrivProtectedData/10_LimitedDataSets.asp. Accessed on December 18, 2006.

Covance believes that the current limitations on the specific uses of LDS data provide a way to allow important research, public health, and health services activities to continue in a manner consistent with the privacy protections of the Privacy Rule. We also believe the current DUA provides sufficient protections for privacy and confidentiality of the data, and that further restrictions would not be appropriate.

Recommendation 3: Covance recommends that LDS versions of the CCW and other Part D-related claims data be consistent with other CMS LDS files.

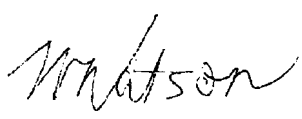
Although the Proposed Rule indicates that CMS plans to make available Part D claims data linked to other Medicare claims data, it does not address whether the CCW or other Part D-related claims data will be similar to other CMS data files in terms of providing the ability for researchers to perform longitudinal analyses with the data. We recommend the standard encryption of patient identifiers to allow for longitudinal analyses of Medicare beneficiaries across settings of care and over multiple years. That is, an identified cohort of patients (for example, patients with a specific diagnosis code) should be the same across different LDS files (including Part D-related claims data) and over time. The standard encryption used for the LDS SAFs allow for such longitudinal analyses and would be an excellent model for LDS versions of the CCW and other Part D-related claims data.

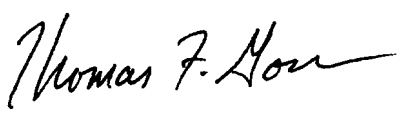
The Proposed Rule also does not mention sample-size considerations for the CCW and other Part D-related claims data. If it is not possible to release 100 percent of the entire Part D claims data set, CMS should provide a sufficiently large sample of data to allow analyses of Part D data to produce statistically reliable national estimates. For example, we recommend the availability of 100-percent data files for specific disease areas or drug classes, and for specific geographic areas (such as selected states).

* * * * *

We hope that you find these comments helpful as you continue to evaluate issues related to collection and use of Part D data. If you have any questions regarding our comments, please contact Wendy Watson at 240/632-3476, John Carlsen at 240/632-3548, or Thomas Goss at 240/632-3224.

Sincerely,





Wendy Watson
Senior Research Analyst

John Carlsen, MHA
Principal

Thomas F. Goss, PharmD
Vice President

Submitter : Mrs. Martha Roherty **Date:** 12/18/2006

Organization : National Association of State Medicaid Directors

Category : Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-89-Attach-1.PDF

NASMD
National Association of State Medicaid Directors
an affiliate of the American Public Human Services Association

December 18, 2006

Leslie V. Norwalk, Esq.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Mail Stop: C4-26-05
Baltimore, MD 21244-1850

Attention: **CMS–4119-P**

Re: Proposed Rule with Comment Period: Medicare Program; Medicare Part D Data

Dear Ms. Norwalk:

The American Public Human Services Association and its affiliate, the National Association of State Medicaid Directors (NASMD), respectfully submit this comment letter on the use of claims information that is now being collected for Part D payment purposes. On behalf of the Medicaid directors in the fifty states and the District of Columbia, APHSA is commenting on the proposed rule published in the October 18, 2006, *Federal Register* (71 *FR* 61455) for the Centers for Medicare and Medicaid Services (CMS). Please be assured that the state Medicaid agencies are fully committed to assisting in the implementation of the Part D program as it relates to individuals who are dually eligible for Medicare and Medicaid.

We appreciate that CMS is utilizing the authority under the Social Security Act to provide for the collection of claims information for research, internal analysis, oversight and public health purposes. We believe that the proposed rule could help clarify this authority and lead to a more efficient system of care for all Medicare Part D enrollees, particularly those eligible for Medicare and Medicaid. We also were pleased to note that you are considering reporting statistics on issues such as the experience of Medicaid beneficiaries as they transitioned from Medicaid to Medicare Part D for their prescription drug coverage.

However, states believe this regulation falls short of achieving its stated goal. As such, we respectfully request that CMS amend the proposed regulation. As noted in our comments below, we believe the proposed rule should take the additional step of including state Medicaid programs among the entities that have access to the data.

Medicaid Coverage for Dual Eligible Beneficiaries

Medicaid has a responsibility to cover certain health care costs for individuals who are dually eligible for Medicare and Medicaid, or "dual eligibles." Dual eligibles have lower incomes and a wide range of physical and mental health needs with more adverse health conditions than other Medicare beneficiaries. It also has been documented that providing health care services for dual eligibles costs twice as much as for other Medicare beneficiaries. (Medicare Payment Advisory Commission, Data Book, June 2006, URL Available at:
http://www.medpac.gov/publications/congressional_reports/Jun06DataBookSec3.pdf)

Currently, Medicaid serves as the safety net for these individuals. That is, Medicaid not only pays for Part A and/or Part B premiums and other Medicare cost-sharing, but also covers certain services not covered under Medicare. In addition, Medicaid currently is the major payer for long-term care services for this population. Particularly relevant to the proposed rule at issue, states continue to make a significant contribution to the costs of drugs for dual eligibles through the monthly state phased down payment, commonly referred to as the "clawback."

Although dual eligibles represent 14 percent of Medicaid's enrollment and account for 40 percent of all Medicaid spending, states have taken significant steps in recent years to improve the coordination of care and achieve cost efficiencies for dual eligibles. In recent years, states have improved upon existing or implemented new systems to coordinate care in their Medicaid programs, particularly for dually eligible individuals.

CMS Guidance to States on Disease Management Programs

The February 25, 2004 Centers for Medicare and Medicaid Services letter to state Medicaid directors specifically encouraged states to "take advantage of the opportunities disease management programs offer to provide coordinated, cost-effective care that improves the health of Medicaid beneficiaries." States have leveraged this guidance and the tools provided in CMS' letter to implement disease management programs that have helped to significantly improve the care delivered to Medicaid beneficiaries with chronic conditions, including dual eligibles. As stated in the guidance, some of the components of a disease management program include:

- Identification of patients and matching the intervention with need;
- Support for adherence to evidence-based medical practice guidelines, including providing medical treatment guidelines to physicians and other providers, and providing support services to assist the physician in monitoring the patient;

- Services designed to enhance patient management, and adherence to an individualized treatment plan (e.g., patient education, monitoring and reminders, and behavior modification programs aimed at encouraging lifestyle changes);
- Routine reporting and feedback loops (may include communication with patient, physician, health plan and ancillary providers, and practice profiling); and
- Collection and analysis of process and outcome measures.

States have utilized this guidance from CMS and developed disease management programs that incorporate medical services, including services at the pharmacy and pharmacist levels. States also have implemented systems to monitor beneficiaries', including duals, medication regimens, and they are leveraging this data to trigger interventions and follow-up as necessary. For example, data on central nervous system drugs, cardiovascular agents, gastrointestinal agents, anti-infective agents, antipsychotics, antidepressants, ulcer drugs and others can provide critical insights into disease management and medical services that dual eligibles may require that may be covered by Medicaid. Further, the experience of states demonstrates that access to the most current medications is often of paramount importance to maintain dual eligibles health and functioning. The result, in many cases, has been improved health outcomes.

Health Outcomes for Dual Eligibles

With the implementation of the Medicare Part D prescription drug program on January 1, 2006, the provision of health care for dual eligibles became more complicated with three separate programs providing for their health care – Medicare, Medicaid and Part D plans. At that time, states also lost a significant tool in managing the totality of dual eligibles' health care – information regarding their prescription drug utilization and spending. Further, in some situations, Medicaid programs may continue to cover some drugs that are not available under Part D plans.

With neither the beneficiary's Medicare Part D plan nor Medicaid possessing the complete profile for the patient's drug regimen, states are concerned that this may lead to an increase in the frequency of adverse interactions and inappropriate care. At a minimum, there will be a lack of coordination that could lead to significant inefficiencies in the Medicare and Medicaid programs. This is contrary to at least one of Congress' stated reasons for enacting the Medicare Part D program referenced in the proposed rule, which was to ensure that "by lowering the cost of critical prescription drugs, seniors will be better able to manage their health care, and ultimately live longer, healthier lives." States believe this can only be achieved if Medicaid, which is responsible for the medical care for many dually eligible beneficiaries, is once again provided with information on prescription drug usage.

Providing states with access to this information would help them to assist dually eligible beneficiaries obtain the medications that are medically necessary without any problems due to systems errors or due to restrictions imposed by the Medicare Part D prescription

drug plans. Although states may be able to obtain some of this information through direct interactions with dual eligibles, as it could with any individual, this may lead to incomplete or inaccurate information. Instead, it would be invaluable for Medicaid staff involved in care coordination efforts for duals to be able to review pharmacy claims data which in turn would inform them of the drugs the enrollee obtained. Specifically, the addition of Medicare Part D pharmacy claims data would greatly enhance the ability to:

- Verify that the recipient has obtained their medication;
- Verify what medication the enrollee has actually obtained compared to those the physician has prescribed (in situations where care coordinators are collaborating with practitioners);
- Facilitate discussion with enrollee's practitioners regarding enrollee's compliance, needs, drug side effects, condition change;
- Facilitate physician adherence to evidence-based standards of care; and
- Facilitate discussion with the enrollee and opportunities for education to promote self management of their chronic disease.

The proposed rule indicates that CMS will utilize this data for studies of the impact of drug coverage on Medicare beneficiaries, spending for other Medicare health care services, efforts to improve the quality of health care services for Medicare beneficiaries with chronic illnesses, efforts to address health disparities by understanding how drugs are being used and how well they work in minority populations and in other populations, among other purposes. Currently, Medicaid agencies are better positioned to evaluate how Medicare Part D prescription drug plan formularies impact the patient and the cost savings that may be generated across the entire spectrum of health care services delivered to the beneficiary. Clearly, useful research information that could document or at some future point lead to positive health outcomes is unlikely to be achieved for dual eligibles if Medicaid programs do not have access to the Part D drug utilization information.

Finally, there is a significant cost efficiency component that has implications for the federal government and states. Despite Medicare Part D's new role in providing prescription drug coverage for dual eligibles, states recognize their ongoing obligation to facilitate the provision of cost efficient care to dual eligibles. As noted earlier, states must make monthly contributions toward prescription drug coverage for dual eligibles, and in the future, this payment is expected to be based on actual drug expenditures of Part D enrollees. States recognize that the provision of medical services and care coordination and disease management programs are closely linked with prescription drug regimens, with each contributing to better health outcomes which in turn can help lower overall costs. Thus, it is incumbent upon CMS to ensure that states regain access to this information if these goals are to be achieved with respect to dual eligibles.

Given this information and the progress that states have made in improving care for dual eligibles, we request that CMS utilize its authority and amend the proposed rule to provide states with access to the drug utilization and spending data collected by the Medicare Part D prescription drug plans. In many ways, our nation's health care system is already a fragmented one. Excluding Medicaid from accessing prescription drug

information for dual eligibles only perpetuates this fragmentation. Under the current proposed rule, information about dual eligibles' prescription drug usage will remain scattered among different providers, facilities, and insurers. As a result, we believe the Medicare and Medicaid programs are taking a step backwards and reversing the progress Medicaid has made to reduce episodic care and facilitate coordinated care and disease management.

Instead, by providing states with access to this information, Medicaid could begin to repair the links and information gaps that were severed upon implementation of Part D. As a result, state Medicaid programs could strengthen their care coordination and disease management initiatives and once again determine which interventions may be necessary and most appropriate.

We would be pleased to meet with you at any time or provide any additional information that may helpful to you on these matters. Thank you for considering our comments. If you have any questions, please do not hesitate to contact Martha Roherty, Director of NASMD, at (202) 682-0100.

Sincerely,

Jerry W. Friedman
Executive Director
American Public Human Services Association

Nancy V. Atkins
Chair
NASMD Executive Committee

Submitter : Dr. Robert Califf **Date:** 12/18/2006

Organization : Duke University Medical Center

Category : Academic

Issue Areas/Comments

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

We agree with the purposes set forth in the proposed rule: reporting to Congress, conducting evaluations of the Medicare program, making legislative proposals, and conducting demonstration projects/making recommendations for improving the Medicare program. In addition, we urge CMS to add an explicit purpose regarding the use of these data for detecting and analyzing the intended and unintended consequences of prescription medication use under actual clinical conditions.

Several recent examples of drugs removed from the market (e.g., Vioxx, Baycol) because of unexpected toxicity once the drugs were in broad use in the population underscore the significance of these issues. The nation urgently needs information on the effectiveness and safety of drugs both in broad populations and in those comprising higher risk patients (e.g., the very elderly, patients with multiple comorbidities, and patients taking numerous medications simultaneously). The Part D prescription event (i.e., claims) data will supplement information that is collected before FDA approval in clinical trials of new drugs, which are often limited to patients without multiple diseases or numerous concomitant medications.

Although language describing the importance of collecting data for this purpose appears in this proposed rule, it is predominantly in the section on Sharing Data with Entities Outside of CMS. While having such language is critical to justify the importance of these data to outside agencies, given the missions of AHRQ, CDC, FDA, HRSA and NIH, and to academic researchers, the overarching goal of protecting the health of Medicare beneficiaries argues that similar language should appear as well in the section regarding Purpose of CMS Collecting Information. We urge CMS to insert such language in this section to signify CMS s objectives of protecting the health and wellbeing of beneficiaries, even though other agencies and external researchers may operationalize those objectives.

GENERAL

GENERAL

See Attachment.

Information to be Collected

Information to be Collected

We are very pleased with the proposal to make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality. [FR page 61453, column 1] The existing terms and procedures have made possible research on numerous questions that have contributed to very significant improvements in the health of many in this nation not only Medicare beneficiaries. Many of these come from prior work linking Medicaid prescription drug claims to claims for other services and other datasets, such as vital statistics.

The availability of Medicare Part D data, which can be linked with other data on Medicaid and Medicare services, is essential to AHRQ, CMS, FDA and NIH if they are to be able to carry out their respective missions. Part D provides an opportunity for the largest person-specific database on medication use among elderly and disabled populations in the United States. When these data are linked with other Medicare health information (e.g., hospitalizations; emergency room visits; clinic or physician office visits), the resulting information, covering now a more complete picture of the care rendered for episodes of illness, can be used by researchers in numerous ways of benefit to patients and society as a whole. Although prescription drug claims files by themselves lack the diagnostic, outcomes and other information to support the needed studies, when merged with other data they can become a powerful tool for improving public health by building a knowledge base on outcomes, positive and negative.

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 Parts A and B data, but also to other data on outcomes, context, and clinical characteristics of beneficiaries. Key examples of these additional data include the following: 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 health care resources of communities; information on characteristics of providers (e.g., use of primary medical care versus specialty care); and Medicaid data on health care encounters and services not covered by Medicare.

Such information is essential 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 confounding by indication or contraindication. Examples of the issues that investigators can address include drug safety (e.g., effects of antipsychotic agents on the development of diabetes), the effectiveness and comparative effectiveness of medications in real-world settings, and the effects of drug coverage and cost containment (e.g., cost-sharing) on Medicare costs and the health of vulnerable elderly and disabled persons. Researchers can also test new interventions to improve medication prescribing and adherence. Such data will not only generate important discoveries about the benefits and harms of prescription medications, but they will also be vitally important to CMS in helping to increase the effectiveness of the drug benefit over time (especially in high-risk populations such as the mentally ill) and to moderate its costs. Furthermore, access to Part D data facilitates our ability to track the use of medications among the most vulnerable populations (e.g., those dually eligible for Medicare and Medicaid) as they transition into the drug benefit.

Limitations

Limitations

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

CMS-4119-P-90-Attach-1.DOC

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

RE: File Code CMS-4119-P

The Centers for Education & Research on Therapeutics (CERTs) investigators appreciate the opportunity to comment on the proposed rule prepared by the CMS related to the use of Medicare Part D claims data. The CERTs program is a national initiative to conduct research and provide education that advances the optimal use of drugs, medical devices, and biological products. The program, which consists of eleven research centers and a coordinating center, is administered as a cooperative agreement by the Agency for Healthcare Research and Quality (AHRQ), in consultation with the U.S. Food and Drug Administration (FDA). The research conducted by the CERTs program has three major aims:

1. To increase awareness of both the uses and risks of new drugs and drug combinations, biological products, and devices, as well as of mechanisms to improve their safe and effective use.
2. To provide clinical information to patients and consumers; health care providers; pharmacists, pharmacy benefit managers, and purchasers; health maintenance organizations (HMOs) and health care delivery systems; insurers; and government agencies.
3. To improve quality while reducing cost of care by increasing the appropriate use of drugs, biological products, and devices and by preventing their adverse effects and consequences of these effects (such as unnecessary hospitalizations).

Our comments are shaped by our experience studying risks, benefits and appropriate use of medications, as well as educating consumers, health care providers and other decision-makers so they can make decisions to improve the health of patients on an individual and population level.

In general we support the proposed rule (42CFR Part 423) regarding access to Medicare Part D Data. The proposal articulates well the pressing need to use Medicare Part D claims to analyze the prescription drug program, conduct research, and report results to safeguard, maintain, and indeed improve the health of Medicare beneficiaries. The proposed rule adequately balances the privacy concerns that beneficiaries may have with the information needed to assure they receive the highest quality care. Safeguards currently in place on the use of claims information for research will adequately protect the confidential private health information of all beneficiaries.

"Purpose of CMS Collecting Information"

We agree with the purposes set forth in the proposed rule: reporting to Congress, conducting evaluations of the Medicare program, making legislative proposals, and conducting demonstration projects/making recommendations for improving the Medicare program. In addition, we urge CMS to add an explicit purpose regarding the use of these data for detecting and analyzing the intended and unintended consequences of prescription medication use under actual clinical conditions.

Several recent examples of drugs removed from the market (e.g., Vioxx, Baycol) because of unexpected toxicity once the drugs were in broad use in the population underscore the significance of these issues. The nation urgently needs information on the effectiveness and safety of drugs both in broad populations and in those comprising higher risk patients (e.g., the very elderly, patients with multiple comorbidities, and patients taking numerous medications simultaneously). The Part D prescription event (i.e., claims) data will supplement information that is collected before FDA approval in clinical trials of new drugs, which are often limited to patients without multiple diseases or numerous concomitant medications.

Although language describing the importance of collecting data for this purpose appears in this proposed rule, it is predominantly in the section on "Sharing Data with Entities Outside of CMS." While having such language is critical to justify the importance of these data to outside agencies, given the missions of AHRQ, CDC, FDA, HRSA and NIH, and to academic researchers, the overarching goal of protecting the health of Medicare beneficiaries argues that similar language should appear as well in the section regarding "Purpose of CMS Collecting Information." We urge CMS to insert such language in this section to signify CMS's objectives of protecting the health and wellbeing of beneficiaries, even though other agencies and external researchers may operationalize those objectives.

"Sharing Data with Entities Outside of CMS"

We are very pleased with the proposal to "make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality." [FR page 61453, column 1] The existing terms and procedures have made possible research on numerous questions that have contributed to very significant improvements in the health of many in this nation – not only Medicare beneficiaries. Many of these come from prior work linking Medicaid prescription drug claims to claims for other services and other datasets, such as vital statistics.

The availability of Medicare Part D data, which can be linked with other data on Medicaid and Medicare services, is essential to AHRQ, CMS, FDA and NIH if they are to be able to carry out their respective missions. Part D provides an opportunity for the largest person-specific database on medication use among elderly and disabled populations in the United States. When these data are linked with other Medicare health information (e.g., hospitalizations; emergency room visits; clinic or physician office visits), the resulting information, covering now a more complete picture of the care rendered for episodes of illness, can be used by researchers in numerous ways

of benefit to patients and society as a whole. Although prescription drug claims files by themselves lack the diagnostic, outcomes and other information to support the needed studies, when merged with other data they can become a powerful tool for improving public health by building a knowledge base on outcomes, positive and negative.

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 Parts A and B data, but also to other data on outcomes, context, and clinical characteristics of beneficiaries. Key examples of these additional data include the following: 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 health care resources of communities; information on characteristics of providers (e.g., use of primary medical care versus specialty care); and Medicaid data on health care encounters and services not covered by Medicare.

Such information is essential 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 confounding by indication or contraindication. Examples of the issues that investigators can address include drug safety (e.g., effects of antipsychotic agents on the development of diabetes), the effectiveness and comparative effectiveness of medications in real-world settings, and the effects of drug coverage and cost containment (e.g., cost-sharing) on Medicare costs and the health of vulnerable elderly and disabled persons. Researchers can also test new interventions to improve medication prescribing and adherence. Such data will not only generate important discoveries about the benefits and harms of prescription medications, but they will also be vitally important to CMS in helping to increase the effectiveness of the drug benefit over time (especially in high-risk populations such as the mentally ill) and to moderate its costs. Furthermore, access to Part D data facilitates our ability to track the use of medications among the most vulnerable populations (e.g., those dually eligible for Medicare and Medicaid) as they transition into the drug benefit.

There have been numerous studies that used linked data to address important public health concerns and to better understand medication risks, appropriate use and the effects of a medication improvement project. For purposes of illustration, following are three such studies completed by CERTs investigators.

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). Note that although the Medicare population is mainly elderly, it does include many women of childbearing age with disabilities. For the elderly population, linkage with vital records will be important to examine the impact of treatments on the risk of hospitalization and death.

In another study, Crystal et al. used prescription drug claims data 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. They found that about two-thirds of those diagnosed received treatment in each year; but those ages 75 and older, those of "Hispanic or other" ethnicity, and those without additional coverage to supplement Medicare were significantly less likely to receive treatment, controlling for other characteristics. The authors concluded that because depression is a major source of potentially treatable morbidity in older people, increased efforts are needed to ensure access to appropriate treatment across all subgroups of older people and to remove economic barriers to treatment. (Crystal, S., U. Sambamoorthi, et al. "Diagnosis and treatment of depression in the elderly Medicare population: predictors, disparities, and trends." J Am Geriatr Soc 51(12): 1718-28, 2003).

In a third example, Pearson and colleagues examined the effects of a prescription monitoring program on benzodiazepine access among Medicaid enrollees living in neighborhoods of different racial composition. They found that the program reduced inappropriate prescribing, with a stronger effect in predominantly black neighborhoods despite lower baseline use. The policy may have resulted in an unintended decrease in nonproblematic use that disproportionately affects black populations. (Pearson SA, Soumerai S, et al. Racial disparities in access after regulatory surveillance of benzodiazepines. Arch Intern Med. 2006 Mar 13;166(5):572-9.)

We also wish to comment explicitly, as requested, on "whether [CMS] should consider additional regulatory limitations for external researchers beyond existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released." [FR page 61453, column 1] We believe, on several grounds, that the existing terms and procedures are sufficient protection against these problems. In particular, the current protocols reflect and rest on longstanding professional and ethical codes of conduct guiding academic research, a well-understood peer review process, and high standards of rigor required of data centers under the data use agreements (DUA). No incidents have ever been published in which CMS data (Parts A or B) were leaked, let alone had adverse consequences. Thus, the existing terms and procedures have stood the test of time for data as private and sensitive as Part D data are assumed to be.

We conjecture that the potential of the data for provider profiling may be among the concerns underlying this particular request for comment. In our judgment, such concerns can be allayed while preserving the proposed rule in its present form without additional regulatory constraints. Provider profiling (identifying individual providers based on measures of the care that they provide) has long been a concern of CMS; however, the current terms and procedures for data use agreements ensure that those requesting data agree not to identify individual providers or release reports identifying individual providers. Standard data use agreements include penalties for not following the letter of the DUA. Commercial misuse of Part D data for provider profiling will fall under these existing procedures.

"Beneficiary Access to Part D Data"

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

We appreciate the opportunity to comment on this proposed rule which clarifies how CMS can use Part D data to improve the quality and safety of care provided to Medicare and other CMS beneficiaries.

Sincerely,

Robert M. Califf, MD
Duke University Medical Center

Elizabeth A. Chrischilles, PhD
University of Iowa

Stephen Crystal, PhD
Rutgers, The State University of New Jersey

Judith M. Kramer, MD, MS
Duke University Medical Center

Daniel C. Malone, PhD, RPh
University of Arizona Health Sciences Center

Alvin I. Mushlin, MD, ScM
Weill Cornell Medical Center

Richard Platt, MD, MS
Harvard Pilgrim Health Care

Wayne A. Ray, PhD
Vanderbilt University Medical Center

Kenneth G. Saag, MD, MSc
University of Alabama at Birmingham

Stephen B. Soumerai, ScD
Harvard Pilgrim Health Care

Alan D. Stiles, MD
University of North Carolina at Chapel Hill

Brian L. Strom, MD, MPH
University of Pennsylvania School of Medicine

Maria E. Suarez-Almazor, MD, PhD
University of Texas MD Anderson Cancer Center

Raymond L. Woosley, MD, PhD
University of Arizona Health Sciences Center

Submitter : Debbie Fritz, Ph.D., M.Ph. **Date:** 12/18/2006

Organization : GlaxoSmithKline

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4119-P-91-Attach-1.PDF

CMS-4119-P-91-Attach-2.PDF

December 18, 2006

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:

GlaxoSmithKline ("GSK") appreciates this opportunity to comment on the Centers for Medicare and Medicaid Services' ("CMS") proposed rule regarding the use of Part D claims data, published in the Federal Register on October 18, 2006 (the "Proposed Rule"),[1] pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA").[2] GSK is a world-leading research-based pharmaceutical company with a mission to improve the quality of human life by enabling people to do more, feel better and live longer. GSK fully supports CMS's proposal to make these Part D claims data available for research and public health purposes.

Elderly Americans are a very important and growing segment of the United States population and have high levels of unmet medical needs. Increasingly afflicted with chronic and other debilitating diseases of aging, this group is the largest user of chronic medications. To improve the health status and healthcare of America's seniors, further research is needed in areas of epidemiology, pharmacoviligance and health outcomes. Such research will help to better assess the extent and natural history of specific diseases, improve monitoring of health events and drug safety and track utilization and outcomes associated with pharmaceuticals and other healthcare services. Currently, one of the greatest challenges to conducting research in this area is the lack of a readily accessible research data source that integrates both medical and pharmacy data on a large, nationally representative population aged 65 years and older.

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

[2] GSK also is a member of both the Pharmaceutical Research and Manufacturers of America ("PhRMA") and the Biotechnology Industry Organization ("BIO") and fully supports those associations' comments to the Proposed Rule.

GSK strongly supports CMS efforts to make these Part D claims data more available, and we believe that these data have the potential to help make healthcare more evidence-based. The proposed availability of a Medicare Part D drug database, both on its own and linked to Medicare Parts A and B data, is an exciting development and will provide a research on the epidemiology of aging, chronic diseases, geriatric drug use, treatment effectiveness and drug safety.

We urge CMS to ensure broad access to the Part D claims data for qualified researchers consistent with the agency's current statutory authority regarding the disclosure of Medicare Part A and B data. In addition, while we believe that these Part D claims data offer tremendous opportunities to augment research that contributes to the public health, we also caution CMS with respect to its own proposed uses to recognize the limitations of retrospective claims data.

Also, we encourage CMS to establish a transparent process for reviewing and approving research conducted with these claims data as well as make public government research priorities and activities related to these data. Finally, GSK requests that CMS clarify that confidential financial information will remain protected from disclosure.

Our detailed comments on these issues are set forth below.

I. Access to Part D Claims Data

GSK supports CMS's efforts to make Part D claims data broadly available to qualified researchers for studies furthering public health knowledge. We urge CMS to continue to make Medicare claims data available to researchers in a manner consistent with the agency's statutory authority and that protects patient privacy. Part D claims data will provide researchers with the ability to further knowledge about senior health and to improve healthcare delivery to America's seniors. The potential benefits of these claims data in furthering medical knowledge are far-reaching and include furthering understanding of disease and treatment, pharmacovigilance efforts, improving safety and efficacy of existing therapies, assessing medication adherence, drug/drug interactions and examining the effectiveness of pharmacy services among different types of providers, regional and geographic patterns of care. For this rich data source to be used in a manner that truly furthers public health knowledge, we believe these data should also be available to private sector researchers, who can provide independent analysis and examination. Accordingly, GSK urges CMS to ensure access to the Part D data to qualified researchers in both the government and the private sector.

GSK supports CMS's existing system for permitting access to external researchers through the use of data use agreements (DUAs) that govern the appropriate uses of the data and ensure that patient privacy is protected. The current DUAs used by CMS for the purposes of releasing Part A and B data to external researchers contain strong protection. We encourage CMS to maintain this process while also seeking to improve the efficiency and effectiveness of the existing DUA process to better expedite data access for new research conducted under an existing DUA. GSK believes that many aspects of the existing process work

well, and we encourage CMS to continue its existing DUA policies to help ensure that data are used for high quality research that benefits the public health and that patient privacy is protected. We support the continued review of research protocols and processes to verify that researchers proposing new protocols have the necessary expertise to perform the research in question. We believe that all researchers – whether government or external – should follow the stringent requirements set forth in the existing DUAs.

In the preamble to the Proposed Rule, CMS expressly seeks comments on the "proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health."[3] CMS also asks "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 ensure that proprietary plan data or confidential beneficiary data is not released."[4]

A wide range of researchers and research entities contribute to the knowledge base that improves healthcare and the public health in this country and elsewhere. Pharmaceutical companies, for example, contribute an abundance of critical research as part of drug development and evaluation. Pharmaceutical companies have well-established research centers and invest billions of dollars each year in clinical, safety, health outcome and epidemiological research on the development of medicines that increase both survival and quality of life in a broad range of therapeutic areas. This research and its attendant information greatly contribute to public health knowledge. Researchers in the pharmaceutical sector focus on issues of critical importance to public health by conducting research on the cause of disease, as well as the diagnosis, prevention and treatment with safe and effective medicines.

In particular, the field of pharmacoepidemiology, long recognized for its contributions in safety and regulatory areas, has had a major impact in improving the public's health. This is consistent with the mission of GSK. In 1982, we established our Worldwide Epidemiology Department to bring population-based evidence on disease, treatments and their outcomes to influence decision-making at all phases of a drug product's lifecycle -- from discovery, through development and to medical practice. This epidemiology focus ensures that GSK has all of the disease-based information and population perspectives that are required to identify, develop, and bring to the marketplace safe and effective medicines that address unmet health needs. Our staff of highly skilled epidemiologists and database analysts is among the largest in the pharmaceutical industry, and we have considerable epidemiology expertise and long-established experience in utilizing claims-based and other observational healthcare databases for epidemiology research.

Our Global Clinical Safety & Pharmacovigilance Department works closely with our Worldwide Epidemiology Department to use claims data to investigate safety signals derived from many sources, including literature, clinical trials, regulatory authorities and routine

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[3] 71 Fed. Reg. at 61453.

[4] *Id.*

aggregate analysis of post marketing data. The elderly population is of particular interest due to a higher risk of adverse events due to co-morbidities, concomitant medications and physiologic changes in the elderly, such as decreased renal function. Our Global Health Outcomes Department also works closely with Worldwide Epidemiology to examine the burden of disease, to assess the harm/benefit ratio of a new medicine, to understand the association between adherence, resource utilization and quality of life to drug treatment. Our Applied Outcomes and Analysis group conducts similar studies in a Managed Care context. This group also assesses the impact of prescription benefit designs and disease management initiatives on health outcomes. Therefore, GSK recognizes the value of the Part D data, both on its own and linked to Part A and B data, to support epidemiology, pharmacovigilance and health outcomes research. This type of research is the methodological cornerstone of public health research that aims to improve the health of the general population.

We urge CMS to continue to allow access for external researchers interested in using Medicare claims data for a broad range of critical research studies that have the potential to increase evidence-based knowledge of pharmaceuticals in the context of broader healthcare research questions. Providing for broad access to these data by qualified researchers will encourage a wide range of research studies that together will improve public health knowledge. GSK also urges CMS to clarify its existing policies on release of Medicare claims data to ensure that external researchers have access to this integrated claims data to conduct research on a broad range of studies that further public health. It is critical that CMS provide equal access to the data, while maintaining appropriate safeguards and protection to ensure the confidentiality of the data and appropriate use.

The agency's existing policy on data use agreements provides a solid framework for permitting external researchers to use the Part D claims data. We urge CMS not to impose additional regulatory limitations on private sector researchers. We believe that CMS should narrowly define the "commercial uses" for which it will not release Medicare claims data. We agree that Part D claims data should not be used to target marketing of products to specific health care providers or for marketing to patients. However, we urge CMS not to unnecessarily restrict the many legitimate uses of these data in which researchers, including private sector researchers, may engage. In the interest of public health, we urge CMS to clearly define the limited excluded uses and to permit data inquiries that are designed to answer a broad range of legitimate research questions of benefit to the public health. Numerous publications from administrative claims database research have contributed to the public knowledge base on disease burden, impact of pharmaceutical therapies on hospitalization or other medical resource utilization offset and healthcare delivery in age groups and ethnic population subsets which may be under-represented in clinical trials.

Private sector researchers, including pharmaceutical companies, health plans, pharmacies and private research centers, should be permitted to access this data for legitimate research questions. For example, GSK is currently conducting a SEER-Medicare study to improve our understanding of cardiovascular and other co-morbidities that have a substantial impact on treatment options, treatment response, quality of life and survival for cancer patients. CMS currently permits external researchers, including pharmaceutical manufacturers, to access

such data for public health purposes. We urge CMS to continue to support legitimate research that adheres to scientifically accepted protocols and standards and furthers public health knowledge by clarifying in the final rule that all qualified external researchers will have access to Medicare claims data.

II. Benefits and Limitations of Claims Data

It is critical that Part D claims data is used appropriately and in a manner that is consistent with current research standards. Health-related retrospective claims databases are an important data source for epidemiology and outcomes research. Yet these retrospective databases also pose methodological challenges. An advantage of many retrospective databases is that they allow researchers to examine medical care utilization as it occurs in routine clinical care. They can provide large study populations and longer observation periods, and this allows for the examination of specific subpopulations. Retrospective databases also offer a relatively inexpensive and efficient way to gather information about specific research questions.[5]

These claims data have the potential to improve healthcare quality by helping to address gaps in existing research, examine care delivery systems and shortcomings and further inquiry into pharmaceutical therapies. Specifically, these data can aid studies designed to improve disease understanding and characterize unmet medical needs by evaluating the occurrence, natural history and burden of disease in the elderly population as well as in specific subpopulations. For example, claims data can augment studies on disease incidence, prevalence, patient demographics, patterns of disease progression, comorbidities, disease risk factors, outcomes and trends or forecasts. Claims data also are useful in drug utilization studies designed to assess treatment patterns and the quality of medication use, including research regarding concomitant medications, appropriate dosing, therapy duration and adherence. Other potential uses of claims data in research include:

- Drug effectiveness studies to assess the beneficial effects of disease treatments in clinical practice;
- Drug safety studies to evaluate and quantify background risks and potential risks of medications in actual clinical use, including identifying risk factors for adverse medical events and studies that contribute to planning and evaluating risk management programs to minimize therapeutic risk;
- Studies of new indications to assess opportunities for possible new drug uses and new paths of drug development;
- Health resource utilization studies to assess the health economic benefits of treatments.

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5 *See* Motheral et al, "A Checklist for Retrospective Database Studies – Report of the ISPOR Task Force on Retrospective Databases", Value In Health, Vol. 6 No.2 2003 at 90).

Yet in using research based on retrospective claims data, it will be critical for researchers and policy makers to understand the limitations of these claims data. Clearly, integrated claims data has the potential to assist researchers in many ways. Yet claims data provide only one piece of the information needed to make healthcare decisions and should not be used in isolation without a thorough understanding of the limits of such data. Typically, claims data are not sufficient to make definitive conclusions or coverage decisions. Instead, research based on claims data can be used to augment other research on the specific research question and address gaps in knowledge. It will be important for CMS to recognize the challenges and limitations of claims data as a research tool and to use this research cautiously in informing any coverage or payment decisions.

Retrospective databases – such as one that combines data from Medicare Parts A, B and D – typically are based on medical claims and were collected for a purpose unrelated to the research studies being conducted. As a result, these databases can lack information on some of the variables that may influence the outcome measures being studied. It is particularly important that studies involving this type of claims data be carefully designed, ideally through a rigorous peer review process to ensure that the data analysis plan was developed appropriately. For example, a patient likely receives a particular medication due in part to the patient's clinical characteristics, including their primary diagnosis and any comorbidities, as well as physician prescribing practices. The database may not contain complete information on both of these components, however, and this can lead to biased estimates. Researchers must design their studies to account for such possible biases. It also is critical that a study be designed in a manner that accounts for the effects of all variables that have an important influence on the outcomes being studied in order to avoid biased estimates of treatment effects. Study designs should control for comorbidities and disease severity using commonly accepted risk adjustment techniques that are appropriate for the Medicare population and the disease being studied.

In addition to urging caution in the utilization of research based on retrospective claims data, GSK urges CMS to ensure that all researchers who utilize these data be held to high methodological and ethical standards. Certainly GSK, as a commercial entity, abides by these standards. In particular, a document that may be helpful is the "International Society for Pharmacoeconomics and Outcomes Research's (ISPOR) Checklist for Retrospective Database Studies." We support CMS's goal of ensuring high quality research, and we believe that accomplishing this goal requires both an awareness of the possible limitations of retrospective data research as well as consistent methodological standards among researchers.

III. Transparency of the Process for Reviewing and Approving Research Studies

We request that CMS make available information on the number of external requests it receives for Medicare claims data and the manner in which the agency responds to these requests, such as how research requests are prioritized, the timeliness of the approval process, and the amounts of any fees charged for various types of data. We also believe that the publication of government-generated reports and analyses would be useful, as well as a description of the federal priorities for use of government sponsored research using Medicare

claims data, much as the Agency for Healthcare Research and Quality (AHRQ), regularly publishes its proposed research priorities and seeks public input on those priorities. This transparency will help to ensure that all stakeholders can participate in a public dialogue regarding research priorities. GSK also requests that when analyses of claims data are publicly released or used as part of a public policy decision-making process that the research protocols, analysis plans and data sources used also are made public. This will allow other researchers to replicate and validate the research and will help to place the research in the most appropriate context.

We urge CMS to establish an open and transparent process to allow for external verification and replication of research analyses. This will be particularly critical when claims data is being used to inform coverage or payment decisions for particular items or services.

IV. Protection of Confidential Financial Information

In the Proposed Rule, CMS explains its statutory authority to collect this Part D claims data for purposes not related to payment under Section 1860D-12 of the Social Security Act. CMS sets forth the analysis that the agency has the authority to collect data from Part D plans that the agency finds necessary and appropriate. Under Section 1860D-12, CMS may, through its contracting requirements with Part D plans, collect data without adhering to the restrictions of the data collected under Section 1860D-15, which the agency may use only for payment purposes. In the preamble to the Proposed Rule, CMS also states that this analysis does not affect the applicability of the Trade Secrets Act.[6] We request that CMS clarify that this Section 1860D-12 authority does not permit CMS to override the disclosure limitations found elsewhere in the Part D statute relating to the disclosure of confidential rebate information protected by the Trade Secrets Act or by § 1927 of the Medicaid statute. Section 1927(b)(3)(D) of the Social Security Act expressly protects rebate information that Part D plans must disclose to the Secretary pursuant to § 1860D-2(d)(2) as well as information that Part D plans are required to disclose to the Secretary regarding the amount of fees paid to providers of a plan's medication therapy management programs. We urge CMS to clarify in the final rule that its § 1860D-12 authority does not undermine these § 1927(b)(2)(D) protections of this confidential financial information. The Part D claims data that CMS is proposing to collect and disclose under the Proposed Rule is based on patient-level claims and is distinct from competitively sensitive financial data regarding rebates.

V. Conclusion

As CMS prepares the final rule, we ask the agency to remain focused on the statute's greater purpose: to provide Medicare beneficiaries with important drug therapies in clinically appropriate and cost-effective settings. Patients' access to advanced therapies depends in part on the availability of high quality healthcare research, and the Part D claims data provides

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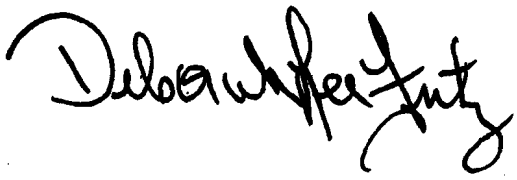
[6] *See* 71 Fed. Reg. at 61453.

an opportunity for greater outcomes research opportunities. By linking the Part D data to the Part A and B claims data, researchers will have a greatly increased ability to conduct safety, pharmacoepidemiologic, economic and outcome studies relating to prescription drugs. In turn, this research will benefit the health of America's seniors. GSK strongly supports the appropriate use of Medicare claims data to reinforce a broad, disease-centered research agenda and to promote quality improvements in the healthcare delivery system. This will allow practitioners to provide more evidence-based care to patients and will help further the development of increasingly effective ways of providing critical healthcare to Medicare patients.

GSK appreciates the opportunity to comment on the issues we have identified in this letter, and we look forward to a final rule that furthers the goal of ensuring Medicare beneficiaries meaningful access to vital drug therapies by increasing the scope of research that is available to inform effective identification and treatment of diseases. Please feel free to contact me at (919) 483-2191 if you have any questions regarding these comments. Thank you for your attention to this very important matter.

Respectfully submitted,



Deborah L. Fritz, Ph.D., MPH
Director, Policy and Healthcare Standards
GlaxoSmithKline

Submitter : **Dr. Michael Pine** **Date: 12/18/2006**

Organization : **Michael Pine and Associates**

Category : **Health Care Industry**

Issue Areas/Comments

Information to be Collected

Information to be Collected

Michael Pine and Associates, Inc. (MPA) wishes to commend CMS for the excellent and insightful analyses provided in the supplementary information section to CMS-4119-P.

MPA is a consulting firm that has specialized in monitoring and improving healthcare quality for almost two decades. MPA has evaluated the effectiveness and efficiency of healthcare services using standard claims data, enhanced administrative data sets, and detailed clinical databases. For more than a decade, MPA was a leading advocate for the incorporation of a present-on-admission modifier in hospital claims. This year, MPA completed research for ARHQ that demonstrated the power of this modifier combined with numerical laboratory data to improve risk-adjustment of inpatient quality indicators and patient safety indicators. MPA has combined and analyzed Part A and Part B data, both as consultants to HCFA (now CMS) and as external users of Medicare data. MPA has been approved to use CCW data to validate a new approach to reimbursing healthcare providers.

Purpose of CMS Collecting Information

From its extensive experience evaluating the quality and cost of healthcare services, MPA has learned the importance of large claims databases in addressing healthcare issues that cannot be addressed adequately by highly-focused clinical trials on relatively small samples of carefully selected patients. The examples contained in the supplementary information section provide a good introduction to the potential utility of incorporating Part D data into such studies. Sharing data with other agencies having particular expertise is essential to obtain all potential benefits for the general public and for Medicare beneficiaries. Restrictions on such sharing should be minimal. As emphasis on transparency increases, public reporting of information that can be obtained from Part D data will be of even greater importance to policy makers, providers, and beneficiaries. MPA has developed and applied techniques from comparative data about healthcare processes and outcomes to guide efforts to improve the effectiveness and efficiency of care. Our experience has confirmed the importance of obtaining data required to aggregate patient-level data by prescribing provider and by plan. The availability of information about filled prescriptions in commercial claims databases has proven to be of great benefit in our comparative studies. We regard its absence as the major deficiency in current CMS databases when they are used to assess and guide improvements in the effectiveness and efficiency of healthcare services.

Sharing Data with Entities Outside of CMS

MPA has practical experience with these large databases both from CMS and from commercial insurers, and has come to appreciate the tremendous value of CMS data in healthcare research. Other governmental agencies and qualified external researchers who wish to undertake investigations important to the health of the nation should not have their access to Part D data restricted beyond current restrictions applicable to Part A and Part B data. CMS clearly is not in a position to make full use these data to learn how best to diagnose and treat disease and manage our out-of-control healthcare system. The addition of Part D data to data from Parts A and B will create a national resource that should not be wasted. In obtaining and using Part A and Part B data, MPA has found the rigor of scientific review and the stringent controls designed to protect confidentiality both daunting and highly appropriate. Similar requirements, rigorously enforced, should prove more than adequate to ensure that Part D data are properly utilized and protected.

Again, MPA commends CMS on its insightful analysis and wholeheartedly supports the proposed rule, CMS-4119-P.

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

Organization : AARP

Category : Other Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-93-Attach-1.PDF

December 17, 2006

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

http://www.cms.hhs.gov/eRulemaking

RE: **Medicare Program; Medicare Part D Data**
71 Federal Register 61445, October 18, 2006

To Whom It May Concern:

Thank you for the opportunity to comment on the proposed rule to allow Part D claims data to be used for purposes other than merely payment of claims. We commend you for proposing this much-needed and well crafted regulation.

We agree that Part D claims data have great value for a multitude of purposes that have potential to help beneficiaries make informed choices. The data can also be used to improve program operation, drug safety, and health care quality overall. We also agree that the data – with necessary and appropriate privacy safeguards – should be made available to other government agencies and outside researchers. We are pleased that the proposed regulation retains the current protections designed to ensure proper use of beneficiary data – including protection of beneficiary privacy.

The specific data elements cited in the proposed regulation section on "Information To Be Collected" – particularly on the details of pricing – are all important and would provide the minimum level of detail needed. We suggest some clarifications, however. For example, "Identification of pharmacy where the prescription was filled" should specify whether it is a traditional, online or mail-order pharmacy, and "Dispensing status" should specify whether it is a new prescription or a refill.

Linking Part D data to Part A and Part B data is also important in a number of ways. Such data can illustrate whether and to what extent drug coverage has affected overall Part A and Part B spending.

Linked data is necessary for determining the extent and impact on beneficiary health and total program costs of potentially decreased compliance with prescription regimens when beneficiaries reach the coverage gap ("doughnut hole"). Linking Parts A, B and D data also is essential for demonstrating the effectiveness of medication therapy management programs, and in enabling Part D plans to target these programs on potential problems in the prescribing practices of individual physicians.

In fact, a key improvement we suggest is to authorize using these linked data (Parts A, B, and D) to assess individual physician performance. This would greatly expand our ability to assess the quality of patient care in several ways:

- As noted in the preamble to the proposed rule, Part D data can help assess appropriate prescribing practices and facilitate initiatives that link physician payment to quality measures.

- External researchers will need physician-specific data – from Parts A, B, and D – if, as the preamble suggests, they are to assist in fulfilling section 723 of the Medicare Modernization Act, which requires the Secretary to develop a plan to improve quality and reduce costs for chronically ill beneficiaries that includes a data warehouse.

- Because of Medicare's size, the physician-specific information that could be shared by combining data from Parts A, B, and D would also help us move towards a system of paying for performance by identifying patterns of inappropriate care, promoting quality improvements and reducing harmful disparities throughout the health care system.

- Additionally, combined data on individual physicians should eventually lead to consumer-friendly performance measures that would help beneficiaries make more informed choices about the physicians who care for them and their families.

We therefore urge you to make clear in the final rule that data on individual physicians will be released. Thank you for considering our comments. If you have any questions, please contact Paul Cotton on our Federal Affairs staff at (202) 434-3770.

Sincerely,

David Certner
Legislative Counsel and Legislative Policy Director
Government Relations and Advocacy