Submitter : Dr. Nancy Kutner **Date:** 12/14/2006

Organization : Emory University

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

This will be a valuable resource for learning about prescription drug usage and the benefits of this usage. It will be especially important as a resource for identifying groups of beneficiaries who are not receiving evidence-based recommended drug therapies, which in turn could help reduce health disparities.

Submitter : **Dr. Christopher Saigal** **Date: 12/14/2006**

Organization : **UCLA/ RAND corporation**

Category : **Physician**

Issue Areas/Comments

Applicability

Applicability

Part D Medicare data

Information to be Collected

Information to be Collected

We believe that CMS should be allowed to share Medicare part D data with the research community in a manner similar to parts A and B. Similar safeguards and access should be maintained. These data would be critical in examining utilization patterns that could identify gaps in care, opportunities for more effective care, or projections in expenditures.

Submitter : Mr. Jason Ormsby **Date:** 12/14/2006

Organization : Joint Commission on Accreditation of Healthcare Or

Category : Health Care Industry

Issue Areas/Comments

Applicability

Applicability

The Joint Commission on Accreditation of Healthcare Organizations welcomes the opportunity to comment on the collection and use of Medicare Part D claims data. Through a proposed rule released October 18, 2006, DHHS (CMS) desires that data, collected for Part D payment, will be used for research, analysis, reporting, and public health functions. Specifically, CMS would use the broad authority under section 1860D-12(b)(3)(D) of the Social Security Act to allow the collection of Part D claims information. This data collection would apply to all Part D sponsors, including prescription drug plan sponsors and Medicare Advantage plans. Internally, CMS desires Part D data for: reports to Congress; conducting evaluations of the Part D program; conducting demonstration projects; supplying the public with overall statistics associated with the drug benefit and making recommendations for improving the economy efficiency, or effectiveness of the Medicare program.

Established in 1951, the Joint Commission is an independent, not-for-profit organization that evaluates and accredits nearly 15,000 healthcare organizations in the U.S. These include hospitals, laboratories, ambulatory care and office-based surgery facilities, and assisted living, behavioral healthcare, home care, hospice, and long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and licensure purposes across all of the Joint Commission s accreditation programs.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

Purpose of CMS Collecting Information
The Joint Commission agrees that the availability of prescription drug claims data from Part D plan sponsors would be invaluable for future healthcare research within CMS. Combining other types of Medicare data (inpatient, outpatient, satisfaction, etc.) with the Part D data would offer a better overall picture of a beneficiary s care and health. Indeed, the absence of Part D data would leave a pool of information that was not sufficient for the studies and operations that the Secretary needs to undertake as part of the [CMS] obligation to oversee the Medicare program, and protect the public health.

GENERAL

GENERAL

See Attachment

Information to be Collected

Information to be Collected

Sharing Data With Entities Outside of CMS
These data would also be invaluable for healthcare research outside of CMS. The Joint Commission strongly supports and encourages the external analysis and evaluation of Part D data. This external assessment is necessary to obtain a better understanding of the quality, efficiency, cost and safety of services provided to Medicare beneficiaries. In the proposed rule, CMS believes that the entities that might need access to the data are:
? government agencies like the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ);
? oversight agencies like the Inspector General (OIG), the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC);
? beneficiaries, and;
? researchers, such as those in universities, to address questions of clinical importance.

Because of the important and unique role the Joint Commission plays in assessing the quality of care for Medicare beneficiaries, the Joint Commission should be provided special status when requesting certain types of Medicare data. According to the proposed rule, in the external researcher category, those seeking Medicare Part D data would need to adhere to the standard data use agreement [DUA] protocols. Although the Joint Commission acknowledges, and strongly supports, the need to protect beneficiary confidentiality, our responsibility for assessing Medicare providers warrants a level of access to Part D data that is separate from the DUA process, and similar to the Joint Commission s current level of access to other types of Medicare data. Joint Commission has had a long partnership with CMS in ensuring the quality and safety of care provided to beneficiaries, as well as protecting the confidentiality of their healthcare information. Additionally, Joint Commission-sponsored research has been widely used by CMS and other government agencies to better evaluate Medicare providers. To properly continue in this oversight role, and to provide timely and germane research, the Joint Commission may require special access to Part D data.

CMS-4119-P-45-Attach-1.DOC

Joint Commission
on Accreditation of Healthcare Organizations

Setting the Standard for Quality in Health Care

December 18, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
CMS-4119-P
P.O. Box 8017
Baltimore, MD 21244-8017

Re: Access to Medicare Part D Claims Data

The Joint Commission on Accreditation of Healthcare Organizations welcomes the opportunity to comment on the collection and use of Medicare Part D claims data. Through a proposed rule released October 18, 2006, DHHS (CMS) desires that data, collected for Part D payment, will be used for research, analysis, reporting, and public health functions. Specifically, CMS would use the broad authority under section 1860D-12(b)(3)(D) of the Social Security Act to allow the collection of Part D claims information. This data collection would apply to all Part D sponsors, including prescription drug plan sponsors and Medicare Advantage plans. Internally, CMS desires Part D data for: reports to Congress; conducting evaluations of the Part D program; conducting demonstration projects; supplying the public with overall statistics associated with the drug benefit and "making recommendations for improving the economy efficiency, or effectiveness of the Medicare program."

Established in 1951, the Joint Commission is an independent, not-for-profit organization that evaluates and accredits nearly 15,000 healthcare organizations in the U.S. These include hospitals, laboratories, ambulatory care and office-based surgery facilities, and assisted living, behavioral healthcare, home care, hospice, and long term care organizations. Although accreditation is voluntary, a variety of federal and state government regulatory bodies recognize and rely upon Joint Commission accreditation decisions and findings for Medicare and licensure purposes across all of the Joint Commission's accreditation programs.

Purpose of CMS Collecting Information

The Joint Commission agrees that the availability of prescription drug claims data from Part D plan sponsors would be invaluable for future healthcare research within CMS. Combining other types of Medicare data (inpatient, outpatient, satisfaction, etc.) with the Part D data would offer a better overall picture of a beneficiary's care and health. Indeed, the absence of Part D data would leave a pool of information that was not "sufficient for the studies and operations that the Secretary needs to undertake as part of the [CMS] obligation to oversee the Medicare program, and protect the public health."

Sharing Data With Entities Outside of CMS

These data would also be invaluable for healthcare research outside of CMS. The Joint Commission strongly supports and encourages the external analysis and evaluation of Part D data. This external assessment is necessary to obtain a better understanding of the quality, efficiency, cost and safety of services provided to Medicare beneficiaries. In the proposed rule, CMS believes that the entities that might need access to the data are:

- government agencies like the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ);
- oversight agencies like the Inspector General (OIG), the Government Accountability Office (GAO) and the Medicare Payment Advisory Commission (MedPAC);
- beneficiaries, and;
- researchers, such as those in universities, to address questions of clinical importance.

Because of the important and unique role the Joint Commission plays in assessing the quality of care for Medicare beneficiaries, the Joint Commission should be provided special status when requesting certain types of Medicare data. According to the proposed rule, in the external researcher category, those seeking Medicare Part D data would need to adhere to the "standard data use agreement [DUA] protocols." Although the Joint Commission acknowledges, and strongly supports, the need to protect beneficiary confidentiality, our responsibility for assessing Medicare providers warrants a level of access to Part D data that is separate from the DUA process, and similar to the Joint Commission's current level of access to other types of Medicare data. Joint Commission has had a long partnership with CMS in ensuring the quality and safety

of care provided to beneficiaries, as well as protecting the confidentiality of their healthcare information. Additionally, Joint Commission-sponsored research has been widely used by CMS and other government agencies to better evaluate Medicare providers. To properly continue in this oversight role, and to provide timely and germane research, the Joint Commission may require special access to Part D data.

Submitter : **Dr. Kara Bambauer** **Date: 12/14/2006**

Organization : **University of Michigan Medical School**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment regarding access and use of Part D data for research purposes

CMS-4119-P-46-Attach-1.PDF

University of Michigan
Medical School

Kara Zivin Bambauer, Ph.D.
Assistant Professor
Mental Health Services
Outcomes & Translation Section

Department of Psychiatry
4250 Plymouth Rd. Box 5765
Ann Arbor, MI 48109
(734) 769-7100 x6009
(734) 761-2617 fax
karabamb@umich.edu

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

To Whom It May Concern:

In order to determine the adequacy of the Medicare drug benefit (Part D) in providing needed prescriptions for some of Medicare's most vulnerable beneficiaries – the elderly and disabled population with mental disorders – it is essential that Part D data be made available for research purposes. Researchers need to be able to determine: 1) who is and is not able to get medications for which disorders; 2) which medications mentally ill beneficiaries either use or cannot access; 3) whether the medications beneficiaries are using are appropriate for their illnesses; as well as 4) what the consequences are of gaps in treatment (such as hospitalizations and ER visits). Examining changes in patterns of medication use and rates of patient adherence to psychotropic and other medications before and after the implementation of Part D will clearly help providers improve the quality of mental health care for Medicare beneficiaries. In addition, it will allow the Centers for Medicare and Medicaid Services to increase the effectiveness of Part D, moderate its costs, and identify beneficiaries at highest risk for problems associated with access and adherence to medicines. Alternatively, without access to this data, researchers, clinicians, and policymakers will be unable to determine the effectiveness, costs, and benefits of providing increased access to millions of beneficiaries, particularly those who are dually eligible for both Medicare and Medicaid. Having access to Part D data is vitally important to the mission and goals of geriatric psychiatrists and mental health practitioners nationwide.

Sincerely,

Kara Zivin Bambauer, Ph.D.
Assistant Professor
University of Michigan Department of Psychiatry

Helen C. Kales, M.D.
Assistant Professor
Geriatric Psychiatry Section
University of Michigan Department of Psychiatry

Frederic C. Blow, Ph.D.
Professor and Director
Mental Health Services Outcomes & Translation Section
University of Michigan Department of Psychiatry

Submitter : **Dr. Srini Beddhu** **Date: 12/14/2006**

Organization : **University of Utah**

Category : **Physician**

Issue Areas/Comments

Information to be Collected

Information to be Collected

The availability of Part D Medicare data to the research community would greatly enhance our understanding of the drug use, adverse events and utility in the actual clinical practice. For example, the RALES study showed that the use of spiranolactone in class IV CHF improves survival. This lead to the increased use of spiranolactone and a subsequent Canadian study that examined the drug use in a Canadian database found an increased incidence of high potassium levels which could be fatal. The ability to track drug use and incidence of diseases using ICD-9 codes has substantial clinical implications.

Submitter : Mr. John Coster **Date:** 12/14/2006

Organization : NACDS

Category : Health Care Provider/Association

Issue Areas/Comments

GENERAL

GENERAL

See attachment

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

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

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

Submitter : Dr. Michael Maves **Date:** 12/14/2006

Organization : American Medical Association

Category : Health Care Professional or Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-49-Attach-1.DOC

AMA
AMERICAN
MEDICAL
ASSOCIATION

Michael D. Maves, MD, MBA, Executive Vice President, CEO

December 14, 2006

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

RE: Proposed Rule and Amendments Concerning the Medicare Program and the Expansion of Medicare Part D Data Uses
File Code CMS-4119-P

Dear Ms. Norwalk:

On behalf of the physician and medical student members of the American Medical Association (AMA), I am submitting for your consideration the following comments on the proposed rule concerning the expansion of CMS' intended uses of the claims data generated under the Medicare Part D Drug Program. 71 FR 61445 (Oct. 18, 2006)

The preamble of the Notice of Proposed Rulemaking, (the "preamble") indicates that the proposed rule would allow the Secretary to link Part D claims data at the individual beneficiary level with claims data from Medicare Parts A and B to create a research database. The database would be used for studies on the impact of drug coverage on Medicare beneficiaries, spending for other Medicare health care services, quality improvement efforts for chronic care populations, efforts to address health disparities, post-market surveillance of pharmaceuticals, and other unspecified studies to improve public health. CMS would allow other agencies and external researchers to access the database.

The proposed rule relies on a generic grant of authority to the Secretary of Health and Human Services (the "Secretary") to include in Part D sponsor contracts any terms or

conditions the Secretary deems necessary and appropriate, including requiring the sponsor to provide such information as may be necessary and appropriate. The proposed rule would amend 42 CFR Chapter IV Part 423 to expand Part D claims data collection, aggregation, use, and release by CMS under the auspices of section 1860D-15 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") beyond those activities necessary for payment. This proposed rule represents a significant expansion of CMS' Part D claims data collection, use, and distribution beyond what is explicitly authorized by Congress under the MMA. Because CMS lacks the requisite statutory authority to adopt the proposed rule, we respectfully urge CMS to rescind this proposed rule.

Statutory Basis for the Proposed Amendment

The MMA does not contain an explicit grant of authority to CMS to engage in the kinds of Part D data collection, use, and distribution practices set forth in the proposed rule. Instead, the agency relies on a generic grant of authority contained within statutes governing contracting practices with Part D plan sponsors to request information for payment purposes.

The preamble notes that the Secretary possesses authority to include in Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate. The preamble notes that this broad grant of authority was incorporated by reference into Part D through section 1860D-12(b)(3)(D) of the MMA from section 1857(e)(1) of the Social Security Act governing contractual arrangements with Medicare + Choice (now Medicare Advantage) plan sponsors. The text of the statute relied upon in this proposed rulemaking follows: "e. Additional Contract Terms. The contract shall contain such other terms and conditions not inconsistent with this part (including requiring the organization to provide the Secretary with such information) as the Secretary may find necessary and appropriate."

The preamble asserts that section 1860D-15, "contains provisions that might be viewed as limiting such collection," which necessitates the promulgation of the proposed rule "in order to resolve the statutory ambiguity." Section 1860D-15(f)(2) states the following: "Restriction on Use of Information. Information disclosed or obtained pursuant to the provisions of this section may 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 this section." The section this refers to is entitled "Subsidies for Part D Eligible Individuals for Qualified Prescription Drug Coverage" and the section is dedicated solely to plan payment. Rather than creating a "statutory ambiguity" necessitating additional rulemaking, 1860D-15(f)(2) is a clear limitation or prohibition against the collection of this data for purposes other than payment and is an explicit restriction on the release of this data to other agencies and outside entities.

The preamble itself recognizes the limitations of the statute relied upon as the authority for the proposed rule. The preamble notes, "Most likely Congress included the broad grant of authority in section 1860D-15 of the Act in order to ensure that the Secretary—without engaging in any rulemaking—would have the legislative authority to collect any necessary data in order to pay Part D sponsors correctly." This recognizes that the statute relied upon

by the agency for this proposed rulemaking was intended to allow for payment and that it does not sanction data collection, use, and distribution for other purposes. While CMS' intention to improve public health through the use of this data may be laudatory, these data practices have not been explicitly authorized by Congress and they represent a significant departure from prior agency data collection, use, and dissemination practices.

Scope of the Proposed Rule

The actual text of the proposed amendment would grant CMS authority exceeding that described in the preamble. The amendment would permit the Secretary to collect drug claims data and related information, as the Secretary deems necessary and appropriate, for purposes including, but not limited to, the following: reporting to Congress and the public on statistics regarding the program's operation; conducting evaluations of the program; making legislative proposals to Congress; and conducting demonstration programs for improving the economy, efficiency, or effectiveness of the Medicare program. It is important to note that the authorized uses enumerated in the rule are not an exhaustive list. As written, CMS would not be constrained from utilizing data collected under this proposed rule for other purposes.

Similarly, the proposed amendment would permit CMS to share the data with other government agencies and outside organizations but does not limit or otherwise identify which agencies or organizations. The proposed rule would operate to immunize CMS from the explicit restrictions on the use of Part D data, set forth in 42 C.F.R. 423.322, which allows data use "only for the purposes of, and to the extent necessary in, carrying out the determination of payments and payment-related oversight and program integrity activities." In essence, the proposed regulatory amendment would expand CMS' authority to use Part D claims data, without explicit limitations on its uses, and allow CMS to release the data to other government agencies and outside entities at the agency's discretion, while explicitly exempting these activities from the requirement that they be related to Part D claims payment.

Because CMS lacks the requisite statutory authority for the expanded data use and dissemination practices that the proposed rule would permit and because these practices represent a significant expansion of the kinds of activities that CMS is currently authorized to undertake, the AMA respectfully urges that CMS rescind the notice of proposed rulemaking. Thank you for your consideration of these comments.

Sincerely,

Michael B. Maves, MD, MBA

Submitter : **Dr. Joan Warre** **Date: 12/14/2006**

Organization : **Dr. Joan Warre**

Category : **Nurse**

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 : **Dr. Bertram Kasiske** **Date: 12/14/2006**

Organization : **University of Minnesota**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

December 14, 2006

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

Dear Sir or Madam:

I am writing to respond to the Proposed Rule, Medicare Program; Medicare Part D Data, published in the Federal Register on October 18, 2006 [CMS-4119-P]. I am the Director of Nephrology at Hennepin County Medical Center in Minneapolis, MN. I am also the Deputy Director of the USRDS, and Editor-in-Chief of the American Journal of Kidney Diseases.
I believe quite strongly that the Secretary should have the authority to use Part D claims information for research, analysis, reporting, and public health functions, and, therefore, support the Proposed Rule.

The Proposed Rule will be an important mechanisms to better understand kidney disease and its costs in the US. There would be little reason not to do this, and much to gain. The Proposed Rule calls for a data sharing agreement that would protect confidentiality of beneficiary information. The data sharing principles should address the patient protections in Privacy Act of 1974, 5 USCA section 552a. There should be specific oversight of merged data requests by the government of ensure the data is used in the best interest of the patients and the public.

Thank you for your attention to these comments.

Sincerely,

Bertram L Kasiske, MD
Director of Nephrology
Hennepin County Medical Center
Professor of Medicine
University of Minnesota

Submitter : Dr. Leslie Greenwald **Date:** 12/14/2006

Organization : RTI International

Category : Academic

Issue Areas/Comments

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond limited payment purposes is reasonable and clearly in the public s interest.
The Secretary s proposal allows for the use of these data, with appropriate review and protections. As the proposed rule notes, CMS is currently responsible for a wide range of program monitoring and evaluation tasks related to the Medicare program. Historically, these CMS functions have been critical in informing policy makers in Congress and elsewhere of both successes and necessary changes to Medicare. As Medicare expands to include the new Part D prescription drug program, ongoing program monitoring and evaluation will be important in understanding how Part D is working, and not working, for Medicare beneficiaries.

GENERAL

GENERAL

As one of CMS s primary research contractors, RTI is currently conducting CMS sponsored work related to Medicare Part D. We can confirm that without the proposed use of Medicare Part D data, these essential monitoring and evaluation functions will not be possible. There are no substitutes available for the Medicare Part D prescription drug data. It is impossible to imagine how restrictions on these data, leading to an inability to effectively monitor and evaluate Medicare Part D would be in the public interest, particularly since use of these data will cause no additional burden on Medicare Part D providers.

Information to be Collected

Information to be Collected

The proposed rule also includes provisions for the use of these data by other government agencies and external researchers. These additional provisions for Part D data use should be allowed. While many Medicare related monitoring and evaluation studies are conducted by CMS or CMS funded contractors, additional valuable research related to the Medicare program is also conducted by other DHHS agencies, congressional entities, and non-government researchers. In an atmosphere of budget restrictions, it is not feasible for CMS or the federal government to fund every relevant and important analyses of Medicare Part D. Therefore, the Part D data, under the proper protections, should be made available to researchers beyond CMS. Fortunately, CMS already has well established protocols for the review of external research proposals and protection of data privacy. These established protocols could be extended to cover the new Medicare Part D data.

Submitter : Dr. Melvin Ingber **Date:** 12/14/2006

Organization : RTI International

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

attachment

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

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

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

Submitter : Dr. Melvin Ingber **Date:** 12/15/2006

Organization : RTI International

Category : Individual

Issue Areas/Comments

GENERAL

GENERAL

attachment

CMS-4119-P-54-Attach-1.DOC

CMS-4119-P-54-Attach-2.DOC

RTI INTERNATIONAL

3040 Cornwallis Road ▪ PO Box 12194 ▪ Research Triangle Park, NC 27709-2194 ▪ USA
Telephone 919 541-6000 ▪ Fax 919 541-5985 ▪ www.rti.org

December 21, 2006

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services (DHHS)
Attention: CMS-4119-P Medicare Program: Medicare Part D Data
P.O. Box 8017
Baltimore, Maryland 21244-8017

Re: Comments on Centers for Medicare and Medicaid Services Proposed Rule

To Whom It May Concern:

In response to CMS's Federal Register notice regarding use of Medicare Part D data (42CFR Part 423), I am writing to express my support and that of my colleagues for the proposed rule and to comment on specific points. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond limited payment purposes is reasonable and clearly in the public's interest.

The Secretary's proposal allows for the use of these data, with appropriate review and protections. As the proposed rule notes, CMS is currently responsible for a wide range of program monitoring and evaluation tasks related to the Medicare program. Historically, these CMS functions have been critical in informing policy makers – in Congress and elsewhere – of both successes and necessary changes to Medicare. As Medicare expands to include the new Part D prescription drug program, ongoing program monitoring and evaluation will be important in understanding how Part D and the program as a whole is working.

The proposed rule envisions a wide array of activities to which these data can be put: reports to Congress, legislative proposals, demonstration projects, evaluations of the Medicare program, and analysis to improve the health and wellbeing of the beneficiary population. These data, along with Part A and B data, can be used in the determination of quality measures, for which there is a strong initiative. Another explicit purpose, not called out in the current rule, envisions use of these data for detecting and analyzing the anticipated benefits and the possible risks or harms of prescription medications under actual conditions of use. We urge CMS to add this purpose unambiguously to the rule, perhaps in the section regarding "Purpose of CMS Collecting Information," to underscore CMS's goal of protecting the health of for the elderly and other Medicare populations.

The proposed rule includes provisions for the use of these data by other government agencies and external researchers. We note the specific language: "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." We strongly support the proposition that CMS should allow these

additional provisions for Part D data use. Although CMS or CMS-funded contractors conduct many Medicare-related monitoring and evaluation studies, other DHHS agencies, congressional entities, and nongovernment researchers also carry out additional, and highly valuable, research related to the Medicare program; this work include investigations directly about appropriate use of therapeutics, particularly pharmaceuticals. We note, as well, that this type of research brings knowledge about issues pertinent to groups other than Medicare beneficiaries, such as populations covered by Medicaid, and thus this research confers benefit to the nation as a whole. In an atmosphere of budget restrictions, it is not feasible for CMS or the federal government to fund every relevant and important analyses of Medicare Part D. Therefore, the Part D data, under the proper protections, should be made available to researchers beyond CMS.

Fortunately, CMS already has well-established protocols for the review of external research proposals and protection of data privacy. These current protocols stem from traditional professional and ethical codes of conduct guiding academic research; they reflect a well-grounded peer review process; and they establish rigorous standards of research conduct that have stood the test of time.

As one of CMS's primary research contractors, RTI is currently conducting CMS-sponsored work related to Medicare Part D. We can confirm that without the proposed use of Medicare Part D data, these essential monitoring and evaluation functions will not be possible to carry out, by us or others. There are no substitutes available for the Medicare Part D prescription drug data, and use of these data will cause no additional burden on Medicare Part D providers.

Restrictions on availability and use of these data, leading to an inability to monitor and evaluate Medicare Part D effectively and to conduct the broader types of studies relating to quality, efficiency, and effectiveness of care (not just for pharmaceuticals) for this critical population, cannot possibly be seen as being in the public interest. We therefore urge CMS to adopt the proposed rule, with the amendments offered above, in the best interests of Medicare beneficiaries and the nation as a whole.

Sincerely,

Melvin J. Ingber

Melvin J. Ingber
Principal Scientist
Division for Health Services and Social Policy Research

Submitter : Dr. Chi-yuan Hsu **Date:** 12/15/2006

Organization : University of California, San Francisco

Category : Physician

Issue Areas/Comments

GENERAL

GENERAL

I support the proposal to allowing linking of Part D data with other types of Medicare data for research use. This will be a unique and valuable resource. This will facilitate the conduct of health services and epidemiology research which will improve health outcomes among Medicare beneficiaries and other Americans.

Submitter : **Date: 12/15/2006**

Organization : **RAND**

Category : **Physician**

Issue Areas/Comments

Information to be Collected

Information to be Collected

Sharing data with entities, including researchers outside of CMS is essential to enable research to be done on how the system is working and how, if at all, it might be strengthened and improved. It is also critical to ensuring the credibility of CMS findings and statements regarding Part D and should be considered part of the Transparency Initiative. Such information can be protected through deidentification and data use agreements.

Submitter : Dr. Marilyn Dix Smith **Date:** 12/15/2006

Organization : ISPOR

Category : Health Care Professional or Association

Issue Areas/Comments

Applicability

Applicability

No Comments

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

No Comments

GENERAL

GENERAL

See Attachment

Information to be Collected

Information to be Collected

We would like to applaud this ruling for recognizing the critical importance of linking the Part D prescription claims at the patient level using the health insurance claim number (HICN) with Part A and B claims. The patient level linkages between these files are critical for most research designs that attempt to identify associations between drug usage and the cadre of possible outcomes measures. We were also excited to see that identifiers are sought for the prescribing health care professional and that there is an attempt to standardize these identifiers in the future which may set standards that can be adopted for plans outside of Medicare. We recognize the efficiency of making data that is already being collected from the Part D sponsors to be the source of the research files for the Part D records and believe the data that are being collected will be adequate for conducting most types of research. On February 28, 2005, ISPOR wrote to Dr. Jeffrey Kelman, to provide comments

on the data elements collected by the Part-D sponsors and we have attached that letter. This ruling clarifies some of the issues raised in that original letter, but we would like to re-iterate a few of those original points.

1. It would be helpful if the original prescription claims files were linked to external files such as First Data Bank or Red Book so that drug name, unit type, therapeutic class, controlled substance status, single/multi source drug, among other measures could be determined and available in the research files. Currently these measures are missing from the proposed data elements and these files could be linked to one of several proprietary sources by national drug code (NDC) to provide this information. Of course the researchers can perform these linkages themselves after obtaining the part D claims, but not all researchers would have access to these external proprietary sources and there would be considerable efficiencies if the research files had these measures already linked by CMS instead of individual researchers purchasing these drug data systems individually.
2. Providing a table that can be linked to the Part D sponsor and part D plan to determine the benefit structure of each of the plans. This would be especially important to identify the tier (copay) structure of the drugs, coverage gaps, and dates when there were any changes to the coverage status of the drugs. This would be critical for conducting many policy analyses.
3. We believe that this section could be improved if CMS made explicit the availability of prescription claims data that could be obtained from Medicare Advantage plans or other non-traditional health plans that offer prescription benefits to Medicare enrollees.
4. These data could also be linked to other national data bases such as the SEER data (as described in section C of the ruling), but also the Medicare Current Beneficiary Survey (MCBS), VA data, and Death Certificate data to name a few of the possibilities.

Limitations

Limitations

No comments

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

We believe that purposes of collecting the Part D data described in this ruling articulate a convincing rationale that we highly support. Specifically, section II.C. of the preamble solicited comments on whether there should be any limitations on data when shared for purposes other than fulfilling CMS s responsibility to administer the Part D program , and we do not feel there need to be any additional limitations not already described in this ruling.

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

We wholly support the overarching goal of this section to make these data available to entities outside of CMS, especially for external researchers outside the federal government. We believe that NIH, FDA, and AHRQ investigators and other federal agencies would have clear needs for utilizing this data to support the

research and evaluations described in this ruling. We highly support making these data available to external researchers and believe that the existing mechanisms to acquire Medicare claims data described provide reasonable assurance that the data would be used properly and protect beneficiary confidentiality. We believe that the Part D data, like the current Part A and B data, should be broadly available to external researchers and believe the same rules that apply to acquiring Part A and B data should also apply to Part D data. Specifically comments were solicited to consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols and we do not believe there need to be any additional regulatory limitations that should apply separately for Part D data.

CMS-4119-P-57-Attach-1.PDF

ISPOR
International Society for Pharmacoeconomics and Outcomes Research
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Email: info@ispor.org Internet: www.ispor.org

December 13, 2006

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

Re: Proposed Rule - Medicare Part D Data

To whom it may concern:

The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) supports making Medicare Part D data available for research purposes. Many of our members are researchers with the expertise to utilize these data to support many types of economic, policy, safety, and epidemiologic investigations that can inform clinical, regulatory, and policy decisions. We share CMS's viewpoint that it is in the interest of public health to share these data. By linking part-D prescription data to medical and inpatient claims already available from CMS, researchers will be in a position to assess health care utilization and outcomes associated with exposure to various drugs. This has not previously been possible for Medicare recipients which represent nearly all geriatric care delivered in the U.S. and an overwhelming portion of the population suffering from many of the most disabling chronic illnesses. The outcomes research generated by these integrated data will also assist CMS in assuring cost-effective choices for drugs that they are ultimately paying for the elderly.

We solicited ISPOR membership in the United States to review the proposed ruling; *Federal Register: October 18, 2006 (Volume 71, Number 201), Proposed Rules, Page 61445-61455.* In this letter, we describe the collective feedback from ISPOR members for the first three sections of the proposed ruling.

A. Information to be collected.

We would like to applaud this ruling for recognizing the critical importance of linking the Part D prescription claims at the patient level using the health insurance claim number (HICN) with Part A and B claims. The patient level linkages between these files are critical for most research designs that attempt to identify associations between drug usage and the cadre of possible outcomes measures. We were also excited to see that identifiers are sought for the prescribing health care professional and that there is an attempt to standardize these identifiers in the future which may set standards that can be adopted for plans outside of Medicare. We recognize the efficiency of making data that is already being collected from the Part D sponsors to be the source of the research files for the Part D records and believe the data that are being collected will be adequate for conducting most types of research. On February 28, 2005, ISPOR wrote to Dr. Jeffrey Kelman, to provide comments

on the data elements collected by the Part-D sponsors and we have attached that letter. This ruling clarifies some of the issues raised in that original letter, but we would like to re-iterate a few of those original points.

1. It would be helpful if the original prescription claims files were linked to external files such as First Data Bank or Red Book so that drug name, unit type, therapeutic class, controlled substance status, single/multi source drug, among other measures could be determined and available in the research files. Currently these measures are missing from the proposed data elements and these files could be linked to one of several proprietary sources by national drug code (NDC) to provide this information. Of course the researchers can perform these linkages themselves after obtaining the part D claims, but not all researchers would have access to these external proprietary sources and there would be considerable efficiencies if the research files had these measures already linked by CMS instead of individual researchers purchasing these drug data systems individually.
2. Providing a table that can be linked to the Part D sponsor and part D plan to determine the benefit structure of each of the plans. This would be especially important to identify the tier (copay) structure of the drugs, coverage gaps, and dates when there were any changes to the coverage status of the drugs. This would be critical for conducting many policy analyses.
3. We believe that this section could be improved if CMS made explicit the availability of prescription claims data that could be obtained from Medicare Advantage plans or other non-traditional health plans that offer prescription benefits to Medicare enrollees.
4. These data could also be linked to other national data bases such as the SEER data (as described in section C of the ruling), but also the Medicare Current Beneficiary Survey (MCBS), VA data, and Death Certificate data to name a few of the possibilities.

B. Purpose of CMS Collecting Information

We believe that purposes of collecting the Part D data described in this ruling articulate a convincing rationale that we highly support. Specifically, section II.C. of the preamble solicited comments on 'whether there should be any limitations on data when shared for purposes other than fulfilling CMS's responsibility to administer the Part D program', and we do not feel there need to be any additional limitations not already described in this ruling.

C. Sharing Data with Entities outside of CMS

We wholly support the overarching goal of this section to make these data available to entities outside of CMS, especially for external researchers outside the federal government. We believe that NIH, FDA, and AHRQ investigators and other federal agencies would have clear needs for utilizing this data to support the research and evaluations described in this ruling. We highly support making these data available to external researchers and believe that the existing mechanisms to acquire Medicare claims data described provide reasonable assurance that the data would be used properly and protect beneficiary confidentiality. We believe that the Part D data, like the current Part A and B data, should be broadly available to external researchers and believe the same rules that apply to acquiring Part A and B data should also apply to Part D data. Specifically comments were solicited to 'consider additional regulatory limitations for external

researchers beyond our existing data use agreement protocols' and we do not believe there need to be any additional regulatory limitations that should apply separately for Part D data.

We thank you for the opportunity to comment on this proposed ruling. If we can be of additional assistance, please let us know.

The signees of this letter represent the Leadership Group of the ISPOR Retrospective Database SIG Group and do not necessarily reflect the views of the broader ISPOR membership; however, the mission of ISPOR is to promote outcomes research and its use in health care decisions and we feel that this proposed CMS ruling is consistent.

If you have any questions regarding our comments, please contact Marilyn Dix Smith PhD, ISPOR Executive Director at mdsmith@ispor.org.

Sincerely,

Leadership Group of the ISPOR Retrospective Database Special Interest Group

Bradley C. Martin, Pharm.D., Ph.D., Professor and Head,Division of Pharmaceutical Evaluation and Policy, University of Arkansas for Medical Sciences

William Crown, Ph.D., President, i3 Innovus, Waltham, MA USA

Michael Johnson, Ph.D., Associate Professor, University of Houston, College of Pharmacy, Houston, TX USA

William D. Marder, Ph.D., Senior Vice President, Thomson Medstat, Cambridge, MA USA

CC: ISPOR Board of Directors

About the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

The International Society for Pharmacoeconomics and Outcomes Research is an international organization promoting the science of pharmacoeconomics and health outcomes research. The International Society is organized to act as a scientific leader relevant to research in pharmacoeconomics, health outcomes assessment, and related issues of public policy. The International Society represents healthcare researchers and practitioners including pharmacists, physicians, economists, nurses and researchers from academia, pharmaceutical industry, government, managed care, health research organizations, and purchasers of healthcare. The mission of the International Society for Pharmacoeconomics and Outcomes Research is to translate pharmacoeconomics and outcomes research into practice to ensure that society allocates scarce healthcare resources wisely, fairly, and efficiently.

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February 28, 2005

Jeffrey Kelman MD
Center for Beneficiary Choices
Office of the Administrator
Center for Medicare & Medicaid Services
Washington, DC

Dear Dr. Kelman,

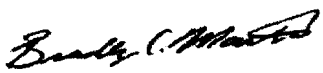
Thank you for the opportunity to comment on the proposed Medicare Part D Prescription Drug Event Record Data Elements. These data will provide exciting outcomes research opportunities and will address one of the shortcomings of using Medicare data for research purposes, namely the inability to have prescription information for the elderly (the largest users of chronic medications). By having these data linked to Medicare part A and B files, there will be a dramatic improvement in our ability to conduct safety, pharmacoepidemiologic, economic, and outcome studies of drugs.

The following are comments and suggestions on the Prescription Drug Event Record Data Elements from ISPOR members, who have experience working with administrative data for research purposes. The comments are organized into four sections:

- **Additional Data Elements and Technical Concerns** – In this section we offer suggestions that would enhance the research applications of the data and would be feasible to implement as part of the prescription claims process.
- **Linkages** – In this section, we raise issues about the ability of the prescription drug event data to be linked to other Medicare files and suggest linkages with other files to expand the usability of data to researchers.
- **Points of Clarification** – In this section, we raise questions about the new Part D benefit and how this benefit will relate to the proposed prescription data elements. We also offer editorial suggestions to the Rx Drug Event Data Paper.
- **Future Directions** – In this section, we offer suggestions that would greatly expand the research applications of these data. These suggestions would require data that are not routinely collected as part of a prescription claims process and provide direction to guide future data collection systems relating to electronic prescription records. We would be interested in working with CMS and NCPDP (National Council for Prescription Drug Programs) to implement these suggestions.

Thank you again for this opportunity. If you have any questions regarding our comments, please contact me directly or the ISPOR office at mdsmith@ispor.org .

Sincerely,



Bradley Martin PharmD, PhD, RPh, Co-chair, ISPOR Database Development Working Group, Retrospective Database Special Interest Group & Professor, College of Pharmacy, University of Arkansas for Medical Sciences, Little Rock, AR [Email: bmartin@uams.edu ; Tel: 501.603.1992]

Benoit Tano MD, PhD, Co-chair, ISPOR Database Development Working Group, Retrospective Database Special Interest Group & Clinical Fellow, Johns Hopkins Asthma and Allergy Center, Baltimore, MD

Michael Johnson PhD, ISPOR Retrospective Database Special Interest Group Co-chair & Assistant Professor, Baylor College of Medicine & Statistician, Houston Center for Quality of Care and Utilization Studies, Michael E. DeBakey VA Medical Center, Houston, TX

William D. Marder PhD, ISPOR Retrospective Database Special Interest Group Co-chair & Senior Vice President & General Manager, Medstat, Cambridge, MA

Cc: Marilyn Dix Smith RPh, PhD, ISPOR Executive Director [Email: mdsmith@ispor.org]

Additional Data Elements and Technical Concerns:

1. In order to comply with HIPPA requirement concerning patient privacy, the following identifiers should be encrypted when used for most research purposes: Health Identification Claim number (HIC# - variable #3), Service Provider ID (variable #7), and Prescriber ID (variable #9). The encryption process should be used with the same encryption protocol on other Medicare claims files so that beneficiary linkages can be constructed for Part A and Part B claims files and enrollment and eligibility files. When necessary and with the appropriate Institutional Review Board (IRB) oversight, researchers should be able to request unencrypted data when the research protocol requires such information to link to other sources.

2. The Product/Service ID (NDC code - variable #11) should be standardized to 11 digits using the 5-4-2 (manufacture-product-package) convention without any missing leading zeros.

3. In addition to the Quantity Dispensed (variable #14), it would be helpful to include a variable defining the unit (e.g. tablets, gram, ml)?

4. A categorical variable to describe the directions for use (i.e. sig) is needed. It is recognized that there may be many possibilities for directions of use, but the most essential information would be the number of units taken per day (i.e. qd, bid, tid) and usage that is 'as needed' (prn).

5. The research application of these data would be enhanced greatly by including a pharmacy provider type variable. The most essential information would be to know if the prescriptions were obtained through 'mail order' and retail sources. The form of delivery is indicative of the patient-pharmacist relationship, an essential aspect of quality monitoring. More precise information for pharmacy provider type could employ the following categorization scheme: mail order, retail chain pharmacy, independent pharmacy, clinic pharmacy, mass merchandiser, grocery pharmacy, other. This information may not necessarily need to be part of the prescription claims adjudication process, but could be linked to NCPDP data sources to provide additional details for each pharmacy provider.

6. Some prescription files contain an indicator variable for 'new', 'refill', and 'partial fill' prescription dispensing and this variable is useful to identify incident therapy of person's first beginning therapy. It would be helpful to include a field such as this in these files.

7. A variable indicating the number of refills remaining would also be helpful to identify adherence issues. We recognize that the number of refills remaining may not be routinely submitted as part of the claims process; however, this information is nearly universally recorded in each pharmacy provider's computer system.

8. For the Product/Service ID (variable #11), multiple values for compounded prescriptions are needed and the NDC should not be limited to the most expensive product? For example, if a product is compounded by a pharmacy, that pharmacy could enter the NDC numbers of each of the products used in the final product.

9. An annual cumulative patient pay amount variable will be useful.

Linkages:

1. It is extremely important that the prescription claims include an encrypted patient identifier that can be linked to each beneficiary's records of the Part A and Part B Medicare claims files. It is assumed that the Health Identification Claim Number (HIC#) would be able to provide that linkage across files.

2. As proposed, there is no drug name or strength. The claims files could be linked to proprietary systems to match NDC to the corresponding name and strength (e.g.: fluoxetine 10mg) of each drug product. Though the researchers could do this after obtaining the claims data, these systems are not available to all researchers and having the prescription product information built in with the NDC codes would be beneficial and make the data more usable to a greater spectrum of potential researchers.

3. The NDC numbers could also be merged with proprietary systems (Multum, First Data Bank) to provide therapeutic classifications, controlled drug schedule class (class I-V), and classifications differentiating single source, innovator multiple source, and non-innovator multiple source drugs. Though the researchers could do this after obtaining the claims data, these systems are not available to all researchers and having the additional information for each drug already built in with the NDC codes would be beneficial and make the data more usable to a greater spectrum of potential researchers.

4. In addition to the Prescriber ID (variable #9), it would be helpful if these identifiers could be linked with Federal (DEA) and or state data with which to build in prescriber specialty (e.g.: internal medicine, neurology, etc.), prescriber locale (state, county, zip), and other prescriber information such as gender, ethnicity, and practice type. We realize this information is not routinely part of a prescription transaction, and such information would likely require linkages to the other sources noted.

5. Learning additional details on the pharmacy provider would provide valuable information to identify the effectiveness of pharmacy services of different providers as well as assess regional and geographic patterns of care. Linking the service provider ID (variable #7) with pharmacy provider information on pharmacy type (mail order, retail chain pharmacy, independent pharmacy, clinic pharmacy, mass merchandiser, grocery pharmacy, other - see comment #5 from Additional Data Elements and Technical Concerns) and pharmacy locale (state, county, zip) would be important.

6. A separate linkable (Plan Benefit Package - variable #2) table describing the formulary and other drug limitations for each plan is essential.

Points of Clarification:

1. Would all the data fields listed be available for research purposes? If not, how would variables be selected to be included in files for research purposes.

2. How will this data relate to persons enrolled in Medicare prepaid managed care plans that offer a prescription benefit? Would those records be included in these files? If so a marker variable flagging such patients will be essential.

3. Could the days supply be greater than 90 days and be reimbursed by Medicare? If this is possible, the Days Supply (variable #15) should accommodate higher days supply.

4. If the same patient switches to other plans but still in Medicare Plan D, theoretically still in the data, will the HIC# remain the same? If not, a unique beneficiary identifier would be important to track changes across plans.

5. Will plans be required to report all electronically issued hard edits in addition to claims? It appears the innovative "Drug Coverage Status" variable will report hard edits on medications acquired within the system, but not for medications that are acquired out of-system. Hard edit records may be indicative of out-of-system care, and necessary for benefit oversight. An extraordinarily high rate of denied claims may also suggest barriers in appropriate care. For example, if authorization is never granted on a prior authorized drug, the plan may never report the acquisition of the drug to CMS as its acquisition is an out-of-system event.

6. Would Date of Birth (variable #4) be provided and be HIPPA compliant with the other supplied information? If date of birth could not be provided, we would suggest providing birth month and year.

7. In the variable list spreadsheet (Table 1), the statement in the "Comment" field doesn't make sense for variable #12.

8. On page 12 of the PDF file, under "Non-covered Part D drug," there appears to be an extra "not" in the phrase regarding "reasonable and necessary."

9. Will there be flat copay tiers (e.g.: $10, $20, $50)? Based on the initial benefit design, the benefit is structured where the patient pays a coinsurance rate (e.g.: 25%). If tiers are being used, this information would need to be available for each Plan Benefit Package (variable #2).

10. Will prescription records for Medicare eligible recipients residing in Nursing Homes and other long term care facilities be recorded in these data? Will there be a variable available to flag these recipients?

Future Directions:

1. Inclusion of a Diagnosis code (Primary Indication) associated with the prescription product. This data element will be helpful to determine the intended use of the product and the patient's disease being treated. We realize that this information is not routinely available on the prescription presented to the pharmacist that dispenses the product, however, as electronic prescribing develops, efforts should be undertaken to include the prescription's intended indications or disease for which the drug was prescribed. This information would be the only way to credibly link diagnostic information to a prescription. As it is now, one must link the files with the medical history files and search diagnoses from medical and inpatient providers and infer a diagnosis. For the more immediate future, this information may be available for instances where a drug may have undergone a prior authorization rule for a certain indication.

2. It would be helpful to collect information for Medication Therapy Management Services (MTMS) provided by a pharmacist. We recognize that the prescription claims file is not designed to contain this information, but patient linkable MTMS data will be essential to evaluate those services.

3. From a research standpoint it would be beneficial to have records for ALL drugs, including over the counter drugs, consumed by Medicare patients and not just those paid for or submitted to the Medicare prescription processors. Because these data are claims data, no mechanism is available to collect prescriptions used outside the Medicare prescription benefit, however, as more integrated electronic tracking systems develop, merging drug purchased outside the Medicare benefit with these claims records is the only way to confidently describe all the drugs potentially consumed by the beneficiary and build reliable observational studies attempting to describe outcome events to particular drug exposures.

4. The Patient Pay Amount (variable #27) could be supplemented with a categorical variable indicating the source of the payment. This would be particularly useful to differentiate payment from State Pharmacy Assistance Programs (SPAPs) and other payment types (self, relative, charity, other).

ISPOR Retrospective Database Special Interest Group Members Responding to the Medicare Part D Rx Event Data Elements

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Aubrey, TX

ISPOR is a nonprofit, international organization that strives to translate pharmacoeconomics and outcomes research into practice to ensure that society allocates scarce health care resources wisely, fairly, and efficiently.

Submitter : **Dr. Ann Nattinger** **Date: 12/15/2006**

Organization : **Dr. Ann Nattinger**

Category : **Physician**

Issue Areas/Comments

GENERAL

GENERAL

I urge the adoption of the proposed rules (CMS-4119-P) in the strongest possible terms.

Information to be Collected

Information to be Collected

I would like to commend CMS on its initiative to propose regulations that would allow release of Part D data to academic researchers. I support the proposed rules (CMS-4119-P) in the strongest possible terms. It is in CMS and its beneficiaries' best interest to allow full access to Part D eligibility, enrollment, and claims data to academic researchers to enable studies examining access, cost, quality, and health outcomes.

As a physician, and a researcher, I understand how important it is to understand the causes and consequences of variation in prescription drug use among Medicare beneficiaries. Understanding the impact of this program on existing treatment patterns and outcomes is of great policy interest. Questions related to the intensity and quality of physician prescribing behavior, innovation, and adherence to evidence-based therapies are critical to examine. Furthermore, it is important to determine the extent to which disparities in care (based on race, socioeconomic status, rural residence, etc) are affected by the Part D program.

Providing entities outside of CMS the access to these data will multiply by many times the rate at which such information can be used to improve the health and healthcare of Medicare beneficiaries and of the American public more generally.

Submitter : Mr. Thomas Snedden **Date:** 12/15/2006

Organization : PA Department of Aging

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-59-Attach-1.TXT

COMMENTS ON
CMS PROPOSED RULE FOR PART D DATA COLLECTION AND USE
AND
PENDING LEGISLATION S. 3897

General

The PACE research team has successfully accessed Medicare Parts A and B data via CMS data use agreement protocols. The data have proven to be a valuable enhancement to the ongoing outcomes evaluation of the program. With regard to data security, the application of the same rules that govern the data protections for Parts A and B are sufficient for obtaining and maintaining Part D data.

The linkage of Part D claims with Parts A and B would be of great value both for program evaluation and pharmaco-epidemiological research. Accessing the Parts A and B data is a complicated process and that alone could be a deterrent to state pharmaceutical assistance programs. However, it is the prohibitive cost of obtaining the data from CMS that poses as an even larger deterrent for state pharmaceutical assistance programs. Sharing the Part D data (and Parts A and B) with entities outside of CMS should be based upon a priority rating of the entities. State pharmacy assistance programs, particularly those designated as qualified SPAPs by CMS, should have a preferential status for accessing CMS data. Preferential status should include priority handling for data retrieval requests and a significant reduction in the cost to obtain the data.

Comparing the Rule to Pending Legislation

Page 6 addresses the specifics found in S. 3897, which is judged to be more prescriptive than the proposed rule. The PACE research team agrees with the spirit of the proposed legislative language to limit Medicare data access to worthy, experienced institutions. However, the team sees that the language could be administered to exclude entities that are not directly identified as university-based research centers that conduct public health research. SPAPs would not fit this definition. Would this language force SPAPs to obtain pre-defined research partners? Point 1 on page 6 provides details for a record of scholarship and publication of results. The PACE research team has begun new areas of inquiry on drug utilization among the elderly. Would some topics be discouraged because of a requirement of scholarship on a given topic? Requirements of any sort with regard to the "publishable" nature of the research would serve to skew proposed research projects. Evaluation research conducted by an SPAP may or may not be intended for publication. Point 3 discusses suitable topics that would appeal to CMS. Would this allow for general scientific inquiry that is focused on the SPAP perspective? Allowable topics should include those topics of value to the SPAPs.

Submitter : Mr. Carl Schmid **Date:** 12/15/2006

Organization : The AIDS Institute

Category : Other

Issue Areas/Comments

Applicability

Applicability

A. Information To Be Collected: The Data Claim elements CMS has outlined in the proposed rule appear to be appropriate and adequate and will be useful in any analysis of the drug benefit for people with HIV/AIDS. Information on the amount paid by the patient and not reimbursed by a third party (such as copayments, coinsurance, or deductibles) all are important information. Additionally, we agree whether the beneficiary has reached the catastrophic coverage threshold is also a valuable data element. We also are interested in the amount of third party payment that would count toward a beneficiary's out of pocket' costs in meeting the catastrophic coverage threshold, such as payments on behalf of a beneficiary by a qualifying State Pharmacy Assistance Program (SPAP) and the reduction in patient liability due to other payers paying on behalf of the beneficiary. This would exclude payers whose payments
count toward a beneficiary's out of pocket costs, such as SPAPs. This information would be particularly useful since payments from state AIDS Drug Assistance Programs (ADAPs) provide wrap around services to the drug benefit, but do not count towards TrOOP. We want to make sure ADAP expenditures are included in your data collection. We also are interested in any low income cost sharing subsidy amounts.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

B. Purpose of CMS Collecting Information: We agree on the importance of collecting the new Medicare Part D prescription drug claims data for studies on 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 which are often not studied in clinical trials, providing protection against adverse drug events through effective post-market surveillance on the safety of drugs for Medicare beneficiaries, and other studies to improve public health. We further agree this database will be an important new tool to facilitate CMS research, on a wide variety of topics that focus on improving the quality of and reducing the cost of health care services.

GENERAL

GENERAL

See Attachment

Information to be Collected

Information to be Collected

C. Sharing Data With Entities Outside of CMS: We understand the potential benefits of sharing the data to outside of CMS entities, such as other agencies within HHS, the GAO, Congress and outside researchers. However, the confidentiality of beneficiaries identify, other personal information, and most importantly, ones HIV/AIDS status must be guaranteed. It is extremely important that the final rule include safeguards protecting beneficiaries confidentiality and elements to protect individual data claims. We would oppose any of the outlined data claims collection if individual confidentiality can not be guaranteed. We are assuming that beneficiary names will not be shared with anyone outside of CMS, but only collective data will be utilized.

CMS-4119-P-60-Attach-1.DOC

THE **AIDS** INSTITUTE

December 15, 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: Comments on Medicare Part D Claims Data Proposed Rule, CMS-4119-P, (*Federal Register*, October 18, 2006, Vol. 71, Number 201, (61445-61455))

Dear Ms. DeBoy and Ms. DeLew:

The AIDS Institute is pleased to comment on the proposed rule issued by CMS in the *Federal Register* of October 18, 2006 regarding Medicare Part D Claims Data.

An estimated 100,000 Medicare beneficiaries living with HIV/AIDS now rely on Medicare for their prescription drug coverage, and it is estimated that nearly 80,000 of them also are dually eligible for Medicaid coverage. By virtue of meeting the eligibility criteria for both programs, the dual eligible population has been disabled for a minimum of two years and they live on very low incomes— generally around $605 a month. Their lives depend on reliable, affordable access to a combination of antiviral medications to treat HIV disease along with a host of medications to address co-occurring conditions and treatment side effects.

We support CMS' efforts to allow the Secretary to collect Medicare Part D claims information for research, internal analysis, oversight, and public health purposes. We are most interested in the data and analysis for beneficiaries with HIV/AIDS, and trust you will be able segment and share the data by those with a HIV or AIDS diagnosis, or at least by beneficiaries taking antiretrovirus medications. We agree the data can be used to "evaluate the new prescription drug benefit, including its effectiveness and impact on health outcomes, performing Congressionally mandated or other demonstration projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the new Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs."

Provisions of the Proposed Rule

A. Information To Be Collected: The Data Claim elements CMS has outlined in the proposed rule appear to be appropriate and adequate and will be useful in any analysis of the drug benefit for people with HIV/AIDS. Information on the amount paid by the patient and not reimbursed by a third party (such as copayments, coinsurance, or deductibles) all are important information. Additionally, we agree whether the beneficiary has reached the catastrophic coverage threshold is also a valuable data

element. We also are interested in the amount of third party payment that would count toward a beneficiary's "out of pocket" costs in meeting the catastrophic coverage threshold, such as payments on behalf of a beneficiary by a qualifying State Pharmacy Assistance Program (SPAP) and the reduction in patient liability due to other payers paying on behalf of the beneficiary. This would exclude payers whose payments count toward a beneficiary's out of pocket costs, such as SPAPs. **This information would be particularly useful since payments from state AIDS Drug Assistance Programs (ADAPs) provide wrap around services to the drug benefit, but do not count towards TrOOP. We want to make sure ADAP expenditures are included in your data collection.** We also are interested in any low income cost sharing subsidy amounts.

B. Purpose of CMS Collecting Information: We agree on the importance of collecting the new Medicare Part D prescription drug claims data for studies on 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 which are often not studied in clinical trials, providing protection against adverse drug events through effective post-market surveillance on the safety of drugs for Medicare beneficiaries, and other studies to improve public health. We further agree this database will be an important new tool to facilitate CMS research, on a wide variety of topics that focus on improving the quality of and reducing the cost of health care services.

C. Sharing Data With Entities Outside of CMS: We understand the potential benefits of sharing the data to outside of CMS entities, such as other agencies within HHS, the GAO, Congress and outside researchers. **However, the confidentiality of beneficiaries' identify, other personal information, and most importantly, ones HIV/AIDS status must be guaranteed. It is extremely important that the final rule include safeguards protecting beneficiaries' confidentiality and elements to protect individual data claims. We would oppose any of the outlined data claims collection if individual confidentiality can not be guaranteed.** We are assuming that beneficiary names will not be shared with anyone outside of CMS, but only collective data will be utilized.

Please contact Carl Schmid, Director of Federal Affairs, The AIDS Institute at (202) 835-8373 should you have any questions regarding our comments.

Sincerely,

Dr. A. Gene Copello
Executive Director
The AIDS Institute
1705 DeSales Street, NW, Suite 700
Washington, DC 20036
(202) 835-8373
gcopello@theaidsinstitute.org

Submitter : Dr. Robert Woodward **Date:** 12/15/2006

Organization : University of New Hampshire

Category : Academic

Issue Areas/Comments

Applicability

Applicability

Generally good. To compare the impact of various plan configurations, it would be useful to include a data element on each claim that reported the (coverage) year-to-date amount spent on allowable prescriptions.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

I support these purposes.

GENERAL

GENERAL

I write to support the implementation of section 1860D 12(b)(3)(D) of the Act to allow the Secretary to collect the same claims information now collected under the authority of section 1860D 15 of the Act
for research, internal analysis, oversight, and public health purposes.

I am a university-based researcher actively involved in using USRDS data to demonstrate that Medicare's coverage of maintenance immunosuppression medications (following kidney transplantation) has eliminated income-related disparities in kidney graft survival. The major gap in these analyses is our lack of knowledge about other medications. Linking Part D data with the existing data from Parts A and B is the only way to evalute appropriately both the effectiveness of Part D coverage among transplant recipients and the impact of other Medicare policies, such as the coverage of immunosuppression medications, while controlling for variances in the use of other medications.

Failing to link these data sets and provide them to independent researchers will substantially increase the costs of evaluating the new prescription drug benefit, including its effectiveness and impact on health outcomes, performing Congressionally mandated or other demonstration projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the new Medicare prescription drug benefit, and studying and reporting on the Medicare program as a whole.

Information to be Collected

Information to be Collected

I support the proposed sharing arrangements and empahsize the role that university researchers play in providing analyses of Medicare cost saving and efficiency improving opportunities.

Submitter : **Dr. John Niederhuber** **Date: 12/15/2006**

Organization : **National Cancer Institute**

Category : **Federal Government**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-62-Attach-1.RTF

I am writing to express the National Cancer Institute's strong support for making Medicare Part D data available for research purposes. NCI and CMS have collaborated for years on the linkage of SEER (Surveillance, Epidemiology, and End Results Program) cancer registry data to Medicare claims. These linked SEER-Medicare data have become an invaluable national resource to assess patterns of care, outcomes, quality measures, and costs of care for Medicare beneficiaries with cancer. Over 200 research articles based on this data resource have been published in peer reviewed journals. These are important sources of information that have an impact on the improvement of care for cancer patients.

A notable gap in the SEER-Medicare data is in the availability of information about prescription drug use in Medicare-eligible cancer patients. Information from Part D data could be used to assess patterns of prescribing for patients with cancer that could provide valuable information about health care-disparities and population-based treatment relative to recommended standards of care. These data would also provide a unique opportunity to assess outcomes following specific drugs therapies for cancer patients. The availability of Part D data is especially important in assessing outcomes, as elderly persons with cancer are often under-represented in clinical trials. As an example, these outcomes could include information pertaining to the potential benefit of a specific drug. In addition, the availability of Part D data in tandem with Medicare Part A and B claims offers a unique opportunity to assess, over the long term, the rates and types and management of adverse events following drug treatment.

In the near future, the Medicare program will face an increasing number of beneficiaries with cancer. Cancer incidence increases with age--and currently persons age 65 and older account for 56% of all cancers diagnosed in the United States. In addition, cancer screening and treatment have improved cancer survival in persons 65 and older, with well over 4.3 million prevalent cases of cancer in this population. Many cancer patients are, and will be, treated with prescription drugs and the cost of these drugs has risen significantly. Although researchers have used Medicare Part A and B data to assess costs of chemotherapy, these earlier studies have been limited as they have not included the costs of oral agents. The availability of Part D data could be used to provide more complete information about the cost of care for cancer patients. Such information would inform and enable policy makers in the future as they plan for the health care needs of Medicare beneficiaries.

In summary, I believe that making Part D data available for research purposes would increase our understanding of treatment and outcomes for cancer patients. The NCI and the cancer research community look forward to working with CMS on the implementation of the research use policies; which will support Medicare in achieving its mission to provide quality, affordable health care to its beneficiaries.

John E. Niederhuber, M.D.
Director, National Cancer Institute

Submitter : Dr. Lawrence Hunsicker **Date:** 12/15/2006

Organization : University of Iowa Carver College of Medicine

Category : Physician

Issue Areas/Comments

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

To evaluate the ultimate impact of an intervention on both the medical outcomes and on the costs of medical care it is necessary to consider not only the proximate outcomes and costs of the intervention, but also the impact on downstream outcomes and costs. For example, the trial group of which I am a member recently demonstrated that blockade of the renin-angiotensin system not only improved the medical outcomes of patients with diabetic kidney disease but was able, through deferral of dialysis, to reduce substantially the costs of their medical care. It will be important in the future to evaluate directly the impact of use of these agents on outcomes and costs of medical care of diabetic kidney disease patients beyond our specific clinical trial study group. More generally, it is clear that understanding the impact of Medicare Part D will require evaluating not only the costs of medicines themselves, but the impact of the use of these medicines on health outcomes and total CMS costs. This can only be done if the drug use and cost data available from the Part D administrative data can be merged with Medicare Part A and Part B data. Thus, I agree that CMS needs to use Medicare Part D prescription drug related data for ... purposes including & conducting evaluations of the Medicare program and conducting demonstration projects & and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.

GENERAL

GENERAL

See Attachment

Information to be Collected

Information to be Collected

I agree also that it is in the interests of public health to share the Part D Medicare data with entities outside of CMS including other government agencies such as NIH, and AHRQ and other external researchers. The availability of CMS administrative data concerning patients with end-stage renal disease to the scientific community through the National Institutes of Health and its contractor, the USRDS, has been a major boon to our understanding of ways to improve the effectiveness and cost-effectiveness of care for ESRD patients and others with chronic kidney disease. The ultimate establishment of a chronic care condition data warehouse (CCW) should extend the benefits of more open access to these CMS administrative data to many other types of patients/conditions. Access of these outside investigators to Part D drug data, in addition to Part A and Part B data, will permit these outside entities to extend their analyses to the optimal and cost-effective use of medicines. Present methods for preserving individual confidentiality and privacy in use for access to the CMS Part A and Part B data have worked extremely well and should be extended, as proposed, to access to the new Part D data.

CMS-4119-P-63-Attach-1.PDF

THE UNIVERSITY OF IOWA

December 15, 2006

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

Re: CMS-4119-P

Dear Sirs and Mesdames:

I should like to support strongly the above proposed rule addressing the use of and access to Part D Medicare data. First let me identify myself. I am Professor of Internal Medicine at the University of Iowa Carver College of Medicine. My primary academic interests have been in the design and performance of controlled clinical trials and in the analysis of large public administrative databases such as the data currently available from the Organ Procurement and Transplantation Network and the United States Renal Data System (USRDS). I have been the Principal Investigator for the USRDS Economic Special Study Center. Some of my current analyses are focused on the late impact of pancreatic transplantation on diabetic eye, heart, and nerve complications, the impact of early referral of patients with chronic kidney disease (CKD) to nephrologists, and the impact of diagnostic studies for cardiovascular disease on post dialysis survival of patients with end-stage renal disease. I mention these specific studies, as they all have direct relevance to optimizing patient outcomes and determining the impact of the above interventions on total costs of care for a group of Medicare eligible patients with severe chronic illnesses. These studies have all been made possible because of access to the CMS Part A and Part B administrative data made available to the research community through the USRDS, one of the NIH contractors.

Purpose of CMS Collecting Information:

To evaluate the ultimate impact of an intervention on both the medical outcomes and on the costs of medical care it is necessary to consider not only the proximate outcomes and costs of the intervention, but also the impact on downstream outcomes and costs. For example, the trial group of which I am a member recently demonstrated that blockade of the renin-angiotensin system not only improved the medical outcomes of patients with diabetic kidney disease but was able, through deferral of dialysis, to reduce substantially the costs of their medical care. It will be important in the future to evaluate directly the impact of use of these agents on outcomes and costs of medical care of diabetic kidney disease patients beyond our specific clinical trial study group. More generally, it is clear that understanding the impact of Medicare Part D will require

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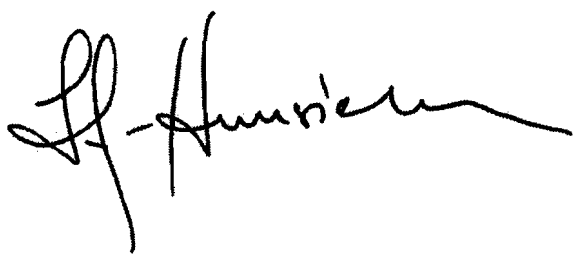
evaluating not only the costs of medicines themselves, but the impact of the use of these medicines on health outcomes and total CMS costs. This can only be done if the drug use and cost data available from the Part D administrative data can be merged with Medicare Part A and Part B data. Thus, I agree that CMS needs to "use Medicare Part D prescription drug related data for ... purposes including ... conducting evaluations of the Medicare program and conducting demonstration projects ... and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program."

Sharing Data with Entities Outside of CMS:

I agree also that "it is in the interests of public health to share the Part D Medicare data with entities outside of CMS" including other government agencies such as NIH, and AHRQ and other external researchers. The availability of CMS administrative data concerning patients with end-stage renal disease to the scientific community through the National Institutes of Health and its contractor, the USRDS, has been a major boon to our understanding of ways to improve the effectiveness and cost-effectiveness of care for ESRD patients and others with chronic kidney disease. The ultimate establishment of a "chronic care condition data warehouse" (CCW) should extend the benefits of more open access to these CMS administrative data to many other types of patients/conditions. Access of these outside investigators to Part D drug data, in addition to Part A and Part B data, will permit these outside entities to extend their analyses to the optimal and cost-effective use of medicines. Present methods for preserving individual confidentiality and privacy in use for access to the CMS Part A and Part B data have worked extremely well and should be extended, as proposed, to access to the new Part D data.

In sum, acceptance of the proposed rule is strongly in the interests of CMS patients and of the country in general. Thank you for the opportunity to comment.

Sincerely yours,



L. G. Hunsicker, M.D.