Submitter : Dr. Grace Lu-Yao **Date:** 11/27/2006

Organization : Cancer Institute of New Jersey

Category : Academic

Issue Areas/Comments

Information to be Collected

Information to be Collected

The availability of Part D data for research purposes could be used to assess:

* Patterns of prescribing for patients with cancer. These patterns could provide information about disparities in health care and population-based treatment relative to recommended standards of care.

* Outcomes following specific drugs therapies for cancer patients. These data could be used to assess the rates and types of and medical management of adverse events following drug treatment. This is important since elderly persons with cancer are often under-represented in clinical trials

* Costs of cancer drugs. Cost of cancer care is a societal concern as the number of elderly increase. Cancer is a disease of the elderly; the total number of cancer cases in the elderly is expected to rise. In addition, people with cancer are surviving longer and may need more ongoing care. The cost of cancer drugs has markedly increased. Rising costs in tandem with increasing numbers of people with cancer will place a significant financial burden on Medicare.

Evaluate risks and benefits of certain prescriptions. Many Rx have side effects. The risks may out weight its benefits in subgroups of patients. The large database will provide valuable resources to idenify pateints who are most likely and least likely to benefit from the Rx.

Submitter : Ms. M Kroyer **Date:** 11/27/2006

Organization : OMRDD

Category : State Government

Issue Areas/Comments

GENERAL

GENERAL

States need Medicare drug data and need it current to be able to evaluate Part D plan formularies across large populations of dually eligible beneficiaries. Even if state organizations supplied CMS with recipient information and CMS provided the data back in a non-recipient specific, aggregate manner, it would be helpful. Medicare drug data is a practical necessity for state organizations working to address the needs of tens of thousands of dually eligible beneficiaries with cognitive impairments.

Submitter : Dr. Heather Gold **Date:** 11/28/2006

Organization : Weill Cornell Medical College/Dept Public Health

Category : Academic

Issue Areas/Comments

Information to be Collected

Information to be Collected

Current Medicare claims data are useful for studying care provided to beneficiaries. One of the big gaps in our knowledge, however, is the variation in use of prescription drugs. By allowing researchers outside CMS to analyze the data, we can study many important issues. For example, I use the linked SEER-Medicare database to study patterns of care for breast cancer patients. Having the Part D data would let us study disparities in and prescribing patterns for cancer patients, providing information about inadequate care and care provided outside clinical trials, where most beneficiaries obtain treatment. We could also study the health and economic outcomes associated with variations in prescription drug use, both of which are important to the Medicare program and growing elderly population. Thank you for your thoughtful consideration of these comments. Respectfully, Heather Taffet Gold, PhD, Weill Cornell Medical College, New York City, NY 10021

Submitter : **Ms. Tracey Moorhead** **Date: 11/28/2006**

Organization : **Disease Management Association of America**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-31-Attach-1.PDF

DMAA

Disease Management Association of America

Leslie Norwalk, Esq.
Acting Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-4119-P
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: CMS-4119-P, Medicare Program; Medicare Part D Claims Data

Dear Ms. Norwalk:

The Disease Management Association of America (DMAA) appreciates the opportunity to submit comments on the Centers for Medicare & Medicaid Services' (CMS) recently issued notice of proposed rulemaking entitled "Medicare Program: Medicare Part D Data" (CMS-4119-P), published in the *Federal Register* on October 18, 2006.

DMAA represents the disease and care management community including disease management organizations, health plans, physician groups, hospital systems, employers, benefit managers and consultants, pharmacy benefit managers, pharmaceutical manufacturers, health care professionals, and academicians. DMAA promotes the role of disease and care management in raising the quality of care, improving health outcomes and reducing health care costs for individuals with chronic conditions.

Comments: Support for Access to CMS Collected Part D Information

DMAA supports the provisions in the proposed rule that would allow Medicare Part D claims information that is now being collected for Part D payment purposes to be accessed and used for other purposes, including supporting CMS demonstrations, pilots and other studies and evaluations of the Medicare program.

The preamble to the proposed rule, on page 61448 of the *Federal Register* notice, highlights a variety of purposes for CMS to collect Part D claims data, including:

- conducting evaluations of the Medicare program;
- conducting demonstration projects and making recommendations for improving the economy, efficiency or effectiveness of the Medicare program; and
- "efforts to improve the quality of health care services for Medicare beneficiaries with chronic illnesses."

701 Pennsylvania Avenue, NW • Suite 700 • Washington, DC 20004 • (202) 737-5980 • (202) 478-5113 fax • www.dmaa.org

To date, lack of access to Part D claims data has had a significant impact on chronic care management organizations participating in CMS demonstration projects and pilots. A specific example is the Medicare Health Support (MHS) pilot, mandated by Congress in Section 721 of the Medicare Modernization Act (MMA), which requires MHS organizations to provide interventions for chronically ill Medicare beneficiaries to improve quality and beneficiary satisfaction, and to reduce costs to the Medicare program.

Access to Medicare pharmacy claims data that is already being collected in a uniform manner by CMS would allow chronic care management organizations to:

- identify and implement timely and appropriate interventions;
- make better use of time spent with beneficiaries by meeting their care needs rather than collecting information; and
- coordinate more effectively with other clinicians, thus improving beneficiary care and outcomes.

Beneficiary-specific Part D data is critical to understanding the overall health of the beneficiary and developing the appropriate interventions in a timely manner, especially as these interventions relate, for example, to medication management or adherence to a medication plan.

The current inability to access Part D claims data has required MHS organizations to rely on less reliable, self-reported beneficiary information. Elderly beneficiaries with multiple complex, chronic conditions may not always accurately or reliably report all of information regarding their medication regimens. Prescriptions may have been ordered by the physician but not filled by the pharmacist. In addition, it is time-consuming, costly and duplicative to collect pharmacy information manually from each beneficiary and validate its accuracy, thus reducing the time available to spend with the beneficiary on interventions that will improve their health. Lack of pharmacy data also impacts the ability of chronic care management organizations to coordinate with physicians and pharmacists, in addition to the accuracy dilemma. All of these issues impact the ability of these organizations to provide timely and accurate interventions that will improve the quality of life and health outcomes for beneficiaries that are enrolled in the Medicare Health Support program.

The NPRM suggests that access to Part D claims data will be available for existing CMS pilots and demonstration projects, however this is not clearly stated. DMAA would request that CMS make clear in the final rule that existing CMS pilots and demonstration projects will be able to access Part D claims data upon the effective date.

Request for Technical Revision:
On a technical note, both the preamble and the proposed regulatory language at 42 CFR 423.505 (f)(iv) refer to CMS "demonstration projects." DMAA recommends inserting the words "and pilot" after the word "demonstration" and before "projects" so that this subsection reads in full:

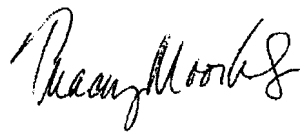
> (f)(iv) Conducting demonstration *and pilot* projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program."

Rationale: As noted above, the preamble discussion references "efforts to improve the quality of health care services for Medicare beneficiaries with chronic illnesses." The Appendix, listing current CMS studies that are underway, discusses projects to evaluate the impact of Congressionally mandated disease management interventions, and specifically cites the MHS pilot that was mandated by Section 721 of the MMA. The addition of "pilot" in the regulatory language would more accurately reflect CMS' intention to allow access to Part D claims data for this purpose. The ability to access reliable and accurate Medicare pharmacy data in a timely manner is crucial to the success of MHS. Access to this data will improve quality, decrease the manual workload, and allow Medicare Health Support organizations to provide better interventions for Medicare beneficiaries.

Our goal is to work collaboratively with CMS to achieve the best results for the CMS, for our member organizations, and most importantly, for the beneficiaries that benefit daily from these programs.

Thank you once again for the opportunity to provide these comments. If you need additional information, please do not hesitate to contact me at (202) 737-5309.

Sincerely,



Tracey Moorhead
Executive Director

Submitter : **Dr. John Loft** **Date: 11/30/2006**

Organization : **RTI International**

Category : **Individual**

Issue Areas/Comments

GENERAL

GENERAL

See attachment

CMS-4119-P-32-Attach-1.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 5, 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:

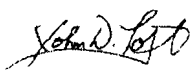
In response to CMS's Federal Register notice regarding use of Medicare Part D data, I am writing to express support for the proposed rule. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond limited payment purposes is reasonable and clearly in the public's interest.

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.

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.

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.

Sincerely,



John D. Loft, PhD
Principal Scientist
Director, Health Services Program
Survey Research Division
Social and Statistical Sciences

Submitter : Mr. Glenn Hackbarth **Date:** 12/01/2006

Organization : MedPAC

Category : Federal Government

Issue Areas/Comments

GENERAL

GENERAL

See attachment.

CMS-4119-P-33-Attach-1.DOC

MEDPAC Medicare Payment Advisory Commission

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202-220-3700 • Fax: 202-220-3759
www.medpac.gov

Glenn M. Hackbarth, J.D., Chairman
Robert D. Reischauer, Ph.D., Vice Chairman
Mark E. Miller, Ph.D., Executive Director

December 1, 2006

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

Re: CMS-4119-P

Dear Ms. Norwalk:

The Medicare Payment Advisory Commission is pleased to submit these comments on the Centers for Medicare & Medicaid Services' proposed rule to allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. We appreciate your staff's ongoing efforts to administer and improve the Medicare program, particularly given the agency's competing demands.

The proposed rule enumerates the various purposes for which the claims information can be used, including reporting to the Congress on the performance of the Part D drug program itself and conducting evaluations of many initiatives intended to improve the quality and reduce the cost of the program. To reduce burden on Part D drug plans and Medicare Advantage plans, the rule would use the existing data stream that goes to CMS rather than requiring these plans to submit the data twice. At the same time, the rule recognizes the need to safeguard the data in accordance with provisions of the law. The rule also would allow CMS to share the information it collects with outside entities, including other government agencies. The preamble to the regulation indicates that these would include Congressional support agencies.

Congressional support agencies are charged with reporting to the Congress about the impact of Medicare payment policies on cost, quality, and access. Data on Part D are necessary for analyzing program performance and making policy recommendations. In its June 2005 Report to the Congress, the Commission recommended that the Secretary have a process in place for timely delivery of Part D data to congressional support agencies to enable them to report to the Congress on the drug benefit's impact on cost, quality, and access.

The Commission commends CMS for its steps to make the data available for evaluation, research, and analysis. These data will prove invaluable; without it, entities would be unable to conduct important activities, such as post-surveillance monitoring of the efficacy of particular drugs, developing performance measures for drug plans, and analyzing the effects of the program on the spending and delivery of health care. The Commission urges CMS to finalize this rulemaking and make the data available as quickly as possible.

MedPAC appreciates the opportunity to comment on this rulemaking. If you have any questions, please feel free to contact Mark Miller, the Commission's Executive Director at (202) 220-3700.

Sincerely,

Glenn M. Hackbarth
Chairman

Submitter : Dr. Austin Frakt **Date:** 12/04/2006

Organization : HCFE

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-34-Attach-1.DOC

HCFE
Health Care Financing & Economics

VA Boston Health Care System Research & Development
150 South Huntington Avenue, Mail Stop 152H, Boston, MA 02130 • Phone: (857) 364-6058 • Fax: (857) 364-4511
http://www.hcfe.research.va.gov

Date: December 3, 2006

To: Centers for Medicare & Medicaid Services

From: Ann Hendricks, PhD, Steve Pizer, PhD, Austin Frakt, PhD, Julia Prentice, PhD

Re: Comments on Proposed Rule, **CMS-4119-P**

We are writing to comment on **CMS-4119-P**, the proposed rule regarding Medicare Part D Data. Our comments pertain to section C, **"Sharing Data with Entities Outside of CMS."**

We support the proposition that CMS "could use and share the claims information [collected] under §423.505(f) with both outside entities and other government agencies, without regard to any restriction included in §423.322(b)."

As academic researchers, we routinely request and analyze Medicare claims and utilization data for our studies. The goals of our research are to understand beneficiary decision-making and utilization patterns and to relate these to clinical outcomes. Our findings have the potential to assist CMS and other policymakers in improving the Medicare program. Because prescription drug utilization is a significant component of the health care beneficiaries receive and plays a major role in health outcomes, it is essential that we be able to link Part D claims to those from Parts A and B.

If the proposed rule is promulgated as drafted, we would be able to conduct studies like the following: 1) A comparison of the costs to the government and health outcomes associated with the inclusion and exclusion of particular drugs on health plan formularies, 2) An analysis of the effect of changes in co-payment structures on beneficiaries' choices of drugs, and 3) A study of the effect of co-payments and coverage limits on beneficiary

compliance with prescribed medication regimes. Studies of this kind have the potential to improve the quality of patient care in general as well as to inform Medicare policymaking.

We strongly encourage CMS to make Medicare Part D claims data files available to external researchers on the same terms as other Medicare Parts A and B data files are released today.

Submitter : Dr. Michael Maddux **Date:** 12/05/2006

Organization : American College of Clinical Pharmacy

Category : Pharmacist

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-35-Attach-1.PDF

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202.756.7506 [fax]
www.accp.com

Department of Government & Professional Affairs

December 5, 2006

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

Reference File Code: CMS-4119-P

Dear Sir or Madam:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to comment on the proposed rule published in the Federal Register on October 16, 2006, that would allow the Health and Human Services (HHS) Secretary to use claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and other public health functions.

ACCP is a national professional and scientific society representing almost 10,000 clinical pharmacist practitioners, researchers and educators. Our members have been among the profession's leaders for almost three decades in developing and providing professional services, consultation, cutting-edge clinical research, and education programs that improve the quality of medication use in the health care settings in which they practice.

It is clear that using claims information already being collected for Part D payment purposes from Part D plan sponsors for purposes other than those related to payments will facilitate better evaluation of the Medicare Part D prescription drug benefit, and better assessment of the impact and effectiveness of Part D expenditures on the overall Medicare program and other government sponsored health programs such as Medicaid or SCHIP. Crucially, these data must be linked at the individual beneficiary level to Part A and Part B claims data in order to determine how the Part D benefit affects broader beneficiary utilization of Medicare program services.

Clear Authority to Analyze Part D Data Can Improve Quality of Care for Medicare Beneficiaries

ACCP recognizes the importance of appropriate analysis of Part D data in order to report to Congress and the public on the overall statistics associated with the operation of the Medicare

Part D benefit, to conduct evaluations of the program, to make and respond to legislative proposals pertaining to Part D and other programs the agency administers, and to develop demonstration projects or other evaluations aimed at improving the economy, efficiency and effectiveness of the Medicare program.

Specifically, the proposed rule would allow a number of government oversight agencies including the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC) access to Part D data to evaluate the cost effectiveness of various policies under the Part D program, evaluate spending on various classes of drugs and to analyze brand-name versus generic prescribing trends.

One of ACCP's core functions is to advance human health and quality of life through research and subsequent practice improvements and as such we strongly support the provision in the proposed rule that would authorize entities outside of CMS to access Part D data.

Medicare Part D Population Considerations
The Medicare Part D population represents unique population demographics which are not usually studied in clinical trials, including older patients, patients with multiple co-morbid diseases and people with a disability. These populations are more likely to experience adverse drug events than other populations, due to their age, relative poor health and because they typically take multiple medications for chronic diseases.

Section 723 of the Medicare Modernization Act (MMA) requires the HHS Secretary to develop a plan to "improve the quality of care for chronically ill Medicare beneficiaries." We are pleased to note that the proposed rule made reference to the creation of a "chronic care data warehouse" (CGW) that would be accessible to private researchers. Some of ACCP's members are well positioned and capable of playing a key role in analyzing and evaluating the utilization of medications under the Part D program, overall expenditures on the Part D program, and how levels of utilization and expenditure impact beneficiaries' therapeutic outcomes, as well as Medicare Part A and Part B, Medicaid, SCHIP and other expenditures. By developing this chronic care database, ACCP believes that CMS can make important steps towards improving the quality of and reducing the cost of health care services.

Identifying and Overcoming Health Care Disparities
One of the greatest challenges in health care delivery is ensuring a consistent level of quality and access to care to all patients nationwide. Because of the unique demographics of the Part D population, the proposed rule on Medicare data represents an opportunity to assess the magnitude of health disparities across geographic or patient demographic lines and in doing so evaluate broader public health issues and identify differences and possible remedial problems with the health care system.

Developing Best Practices for Medication Therapy Management Services (MTMS)
In the final rule implementing the MMA, CMS noted that MTMS must "evolve and become a cornerstone of the Medicare Prescription Drug Benefit." As Medicare Prescription Drug Plans

(PDPs) and Medicare-Advantage Prescription Drug Plans (MA-PDs) continue to develop MTM programs, it is clear that all Medicare stakeholders, including providers of MTMS, payers, beneficiaries and Medicare program administrators need access to data and reports evaluating the effectiveness of MTMS programs and illustrating their impact with regards to clinical outcomes and non-drug health care expenditures.

Evaluating the Impact of Step-Therapy
ACCP supports the development of cost-effective drug utilization management programs such as step-therapy in order to control costs and minimize risks. In order to evaluate the effectiveness of step therapy in achieving these stated outcomes, it is vital that CMS have the ability to evaluate and monitor both costs and health outcomes.

Drug Usage as a Surrogate Measure for the Existence and Severity of Diseases
In the proposed rule, it is noted that Medicare Part D data could be used by the National Institutes for Health (NIH) to investigate the incidence and prevalence of particular diseases, disease progression, and the health outcomes of people with the diseases. However, it is critical that in using drug usage as a surrogate measure for the existence and severity of diseases, NIH must be confident that the utilization of these drugs is appropriate, that the drugs are working and that they are not interacting with other drugs in such a way to negate their positive effects or have an unintended negative consequence.

Since 1997, 1) more than 250 new drugs were approved by the Food and Drug Administration (FDA), 2) the Institutes of Medicine (IOM) released two important reports on issues of preventable errors and needed changes in health care systems, and 3) expenditures on drugs increased by an average of 17% per year. Accordingly, in order for NIH to make informed and appropriate decisions based on drug usage statistics, it is vital that external researchers (including ACCP members) have access to data and can evaluate and analyze drug utilization and outcomes to ensure appropriate and safe usage of medications. Without this, NIH could base their reporting on outcomes that are the result of ineffective or unsafe medication utilization, rather than actual disease patterns.

In summary, ACCP recognizes the importance of clarifying that CMS has full authority to use claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and other public health functions. In addition, we commend the agency for recognizing the role that entities outside of CMS (including other government agencies and external researchers) can play in analyzing data and conducting studies to improve public health:

- To analyze Part D data and monitor a vulnerable population for medication-related issues and plan practices that may result in adverse drug events.
- To allow CMS to fulfill a requirement of the MMA by populating a chronic care data warehouse accessible by external researchers
- To identify and address nationwide health care disparities within the Medicare Part D population
- To help develop models and best practices for MTMS

- To assess the impact and effectiveness of tier structure and plan restrictions such as prior authorization, step-therapy and quantity limits
- To help ensure that drug usage data used to measure the existence and severity of diseases accurately reflect the incidence and prevalence of diseases rather than simply the inappropriate use of medications.

ACCP and its members welcome the opportunity to access and analyze Medicare Part D data for other research, analysis, reporting, and other public health functions in order to help evaluate the Medicare Part D prescription drug benefit, to assess the impact and effectiveness of expenditures under Part D and formulate and propose changes or developments affecting the Medicare program and other government sponsored health programs such as Medicaid or SCHIP. Please feel free to follow up with us at any time.

Sincerely,

M. Maddux

Michael S. Maddux, Pharm. D., FCCP
Executive Director

C. Edwin Webb

C. Edwin Webb, Pharm. D., M.P.H.
Director, Government & Professional Affairs

Cc: ACCP Board of Regents

American College of Clinical Pharmacy • 3101 Broadway, Suite 650 • Kansas City, Missouri 64111-2446 • 816.531.2177
Michael S. Maddux, Pharm.D., FCCP, Executive Director

Submitter : **Edward Drozd** **Date: 12/08/2006**

Organization : **RTI International**

Category : **Individual**

Issue Areas/Comments

Applicability

Applicability

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.

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 those strictly limited to program payments is both reasonable and in the public s interest. As the proposed rule notes, CMS is currently responsible for a wide range of program monitoring and evaluation tasks related to the Medicare program. A great many of these tasks required the use of Medicare claims databases. These program monitoring and evaluation tasks have been critical in informing policy makers and the general public of both successes and necessary changes to Medicare. As with traditional Medicare Fee-For-Service and Medicare Advantage, CMS must be given the ability to conduct monitoring and evaluation on the new Part D prescription drug program to understand how well Part D is working to improve access to prescription drugs to beneficiaries while satisfying its fiduciary responsibilities to taxpayers.

GENERAL

GENERAL

See attachment.

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, important provisions 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, the Congress, 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 for Medicare claims and other privacy-protected data. These established protocols could be extended to cover the new Medicare Part D data.

CMS-4119-P-36-Attach-1.PDF

CMS-4119-P-36-Attach-2.PDF

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 8, 2006

Centers for Medicare & 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, I am writing to express support for the proposed rule. The proposal by the Secretary to allow the use of Medicare Part D data for purposes beyond those strictly limited to program payments is both reasonable and 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. A great many of these tasks required the use of Medicare claims databases. These program monitoring and evaluation tasks have been critical in informing policy makers and the general public of both successes and necessary changes to Medicare. As with traditional Medicare Fee-For-Service and Medicare Advantage, CMS must be given the ability to conduct monitoring and evaluation on the new Part D prescription drug program to understand how well Part D is working to improve access to prescription drugs to beneficiaries while satisfying its fiduciary responsibilities to taxpayers.

The proposed rule also includes provisions for the use of these data by other government agencies and external researchers. These additional, important provisions 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, the Congress, 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 for Medicare claims and other privacy-protected data. These established protocols could be extended to cover the new Medicare Part D data.

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.

Sincerely,

Edward M. Drozd
Senior Research Economist
Division for Health Services and Social Policy Research

Submitter : **Dr. Wayne Anderson** **Date: 12/12/2006**

Organization : **RTI International**

Category : **Academic**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-38-Attach-1.DOC

RTI INTERNATIONAL

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Telephone 919 541-6000 ▪ Fax 919 541-5985 ▪ www.rti.org

December 15, 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 the rule to use Medicare Part D data (42CFR Part 423), I am writing as a member of the broader research community, and as an employee of RTI International, to express my support for the proposed rule and to comment on specific points in the proposed rule. 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. I would like to thank CMS for its work in preparing this proposed rule.

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 crucial for understanding how Part D is working, and not working, for Medicare beneficiaries.

The proposed rule envisions many activities for which these data could be used, including reports to Congress, evaluations of the Medicare program, and generally steps to improve the Medicare program and thereby the health and wellbeing of the beneficiary population. While not named in the current rule, these data could be used to detect and analyze the anticipated benefits and the possible risks or harms of prescription medications under actual conditions of use. I would urge CMS to add this additional purpose to the rule to ensure protection of the health of the elderly and other Medicare populations.

The proposed rule includes provisions for the use of these data by other government agencies and external researchers. I strongly support that Medicare Part D claims data should be able to be used by external researchers and linked to other Medicare claims files on the same

terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality. These data should also be made available to other government agencies and non-government researchers who contribute to research findings to improve the health care of Medicaid and Medicare beneficiaries. 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.

I have focused on analyses of Part D data. However, the use of these data, when linked to Parts A and B claims data, offers an important opportunity to study the quality and efficiency of patient episodes of care – providing a far more useful and telling account of the processes and outcomes of services made available through the Medicare program. Information from analyses that combine Parts A, B, and D will give clinicians and others numerous ways, heretofore unavailable, to improve the quality of care for these patients.

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. Not only do they reflect a well-grounded peer review process, they establish rigorous standards of research conduct that have stood the test of time. We believe that CMS can safely and efficiently extend these established protocols, terms, and procedures to cover the new Medicare Part D data.

As one of CMS's primary research contractors, RTI International 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 would not be possible. 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,

Wayne L. Anderson, Ph.D.
Member
Health, Social and Economics Research Unit

Submitter :

Date: 12/12/2006

Organization :

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-39-Attach-1.DOC

CMS-4119-P-39-Attach-2.DOC

December 15, 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 the rule on use of Medicare Part D data (42CFR Part 423), I am writing to express support for the proposed rule and to comment on specific points in the proposed rule . 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. CMS is to be commended for the careful work that has gone into development of this proposed rule.

The Secretary's proposal will allow 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 to informing policy makers – in Congress and elsewhere – of both the successes and necessary changes needed to the program. As Medicare expands to include the new Part D prescription drug program, ongoing program monitoring and evaluation will be important for understanding how Part D is working and not working for Medicare beneficiaries.

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 generally steps to improve the Medicare program and thereby the health and wellbeing of the beneficiary population. Another explicit purpose, not called out in the current rule, envisions use of these data for detecting and analyzing the benefits and the risks or harms of prescription medications under actual conditions of use. I urge CMS to consider adding this purpose to the rule to underscore CMS's goal of protecting the health of the elderly and other Medicare beneficiaries.

The rule also includes provisions for the use of these data by other government agencies and external researchers. I strongly agree with the intent 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." I strongly support the

proposition that CMS should allow these additional provisions for Part D data use. 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.

While my comments have focused on analyses of Part D data, the utility of these data, when linked to Parts A and B claims data, offers an unequalled opportunity to study the quality and efficiency of episodes of care – providing a far more useful account of the processes and outcomes of services made available through the Medicare program. Information from analyses that combine Parts A, B, and D will give clinicians and others numerous ways, heretofore unavailable, to improve the quality of care for these patients.

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. I believe that CMS can safely and efficiently extend these established protocols to cover the new Medicare Part D data. It is clear that without the proposed use of Medicare Part D data, essential monitoring and evaluation functions will not be possible. 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 as they are being reported anyway.

Availability and use of these data to monitor and evaluate Medicare Part D effectively and to conduct the broader types of studies relating to quality, efficiency, and effectiveness of care for this critical program, can only be viewed as being in the public interest. I therefore urge CMS to adopt the proposed rule with the one addition offered above.

Sincerely,

Arthur J. Bonito, Ph.D.

Submitter : **Date: 12/13/2006**

Organization : **Society for Women's Health Research**

Category : **Other Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-40-Attach-1.DOC

SOCIETY FOR
WOMEN'S HEALTH RESEARCH

December 12, 2006

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

Dear Acting Director Norwalk,

On behalf of the Society for Women's Health Research, we are writing in response to the request for comments on CMS-4119-P "Medicare Program; Medicare Part D Data." The Society has two comments it would like to make regarding necessary data collected and the need for the appropriate use of the terms "sex" and "gender," as well as the subsequent need for sex differences research and analysis.

The Society for Women's Health Research is the nation's only not-for-profit organization whose mission is to improve the health of all women through research, education and advocacy. The Society advocates for increased funding for research on women's health; encourages the study of sex differences that may affect the prevention, diagnosis and treatment of disease; promotes the inclusion of women in medical research studies; and informs women, providers, policy makers and media about contemporary women's health issues.

The Society is encouraged by the data collection intended by CMS under the proposed regulation, as it will be a valuable tool for many avenues of research and analysis. However, in order for the data to be effectively used it must be collected in a consistent manner in keeping with scientific terminology. Specifically, the Society asks that CMS appropriately use and differentiate between the terms "sex" and "gender" in its data collection process.

Scientists have long known of the anatomical differences between the sexes, but only within the past decade have they begun to uncover significant biological and physiological differences between the sexes. Sex differences have been found everywhere from the composition of bone matter and the experience of pain to the metabolism of certain drugs and the rate of neurotransmitter synthesis in the brain.

In April 2001, the Institute of Medicine (IOM) of the National Academy of Sciences released a report entitled, "Exploring the Biological Contributions to Human Health: Does Sex Matter?" The resounding answer was "Yes." The report, initiated and supported by the Society and released by the National Academy of Sciences, found that sex differences important to health and human disease occur in the womb and throughout the life span, affecting behavior, perception, and health.

According to definitions provided by IOM in the report, the term ***sex*** means "the classification of living things, generally as male or female, according to their reproductive organs and functions assigned by chromosomal complement." While ***gender*** is defined as, "a person's self-representation as male or female or how that person is responded to by social institutions on the basis of the individual's gender presentation. Gender is shaped by environment and experience." Sex is thus a scientifically acknowledged biomarker, whereas gender is not. This distinction is incredibly important to biomedical research. The Society feels very strongly that these terms should be used correctly in all government documents.

We have found several instances of the misuse of the term gender, where sex should be used, within the language of the proposed CMS regulation. In *Section II Provisions of the Proposed Rule, Part A. Information to be Collected*, one line reads, "Patient date of birth and gender." This should state **patient date of birth and sex**. Further in Section *II, Part B Purpose of CMS Collecting Information, Sub-section 1 Public Reporting*; there are two more instances of the word "gender" being used instead of "sex." It is the sex of the patient that is being asked for not gender. Interestingly, in *Section II, Part B, Sub-section 4(b) Beneficiary Identifiers*; the term sex is used correctly by its definition. Without being clear and consistent in the terminology, it will be impossible to gain meaningful data on sex differences.

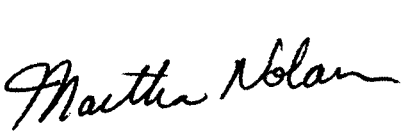
In addition, we urge CMS to ensure that any data collection include the study and examination of biological sex differences. There are many cases in which the benefit of a technology or service will be evident in a specific patient population. In order for specific patient populations, such as women, to benefit from scientific research and the resulting medical treatment or procedures, the appropriate data collection and analysis must be performed to ensure that any important sex differences are understood. Therefore, as CMS evaluates the quality of a proposed study design, we believe it is crucial that all of these proposed designs directly examine sex differences, using the correct terminology and definition of "sex", and timely report this data to CMS.

It is important to note as well, the profound effect this data will have on women. With women making up 56% of Medicare beneficiaries, the obvious avenues of study will help researchers understand many aspects of women's health and sex differences better. We agree that this data has many possible uses and, as the proposed regulation suggests, it should be used to "investigate clinical effectiveness, appropriateness of health care items and services...efficiency and effectiveness of clinical care" and "the safety and efficacy of drugs...with respect to the dose or duration of use" and drug interaction. We fully support the intention to further research and analysis that is intended by this regulation;

we want to ensure part of it is gaining a greater understanding of what makes women and men different.

Thank you for providing this opportunity to comment on CMS's proposed rules on CMS-4119-P "Medicare Program; Medicare Part D Data." We hope that you will take our comments into consideration.

Sincerely,



Phyllis Greenberger
President

Martha Nolan
Vice President of Public Policy

Submitter : **Ms. Valerie Barton** **Date: 12/13/2006**

Organization : **Avalere Health LLC**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-41-Attach-1.PDF

Avalere

December 13, 2006

SUBMITTED ELECTRONICALLY

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

Re: CMS-4119-P – Medicare Program; Medicare Part D Data *(71 Federal Register 61445)*

Dear Ms. Norwalk:

We are pleased to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on use of Medicare Part D claims data, published on October 18, 2006, in the Federal Register. Avalere Health LLC is a leading strategic advisory firm in the healthcare field. The company provides strategy, research, and educational products to a range of commercial and non-profit customers with interests in improving the healthcare system.

Avalere Health supports CMS' goal of making Part D claims data available to researchers both in the government and in the private sector for the purposes of improving the financing and delivery of care to Medicare beneficiaries. Avalere Health also supports CMS' intention to link Part D claims data with existing claims data for Medicare Parts A and B, thus facilitating broader analysis of beneficiaries' health status and utilization of Medicare services. If appropriate research protocols are ensured, research using Medicare claims data can inform improvements in the delivery of healthcare services to all subgroups of Medicare beneficiaries. We encourage CMS to make this data available as soon as possible.

Sharing Data with Entities Outside of CMS
We recommend that CMS continue to use existing Data Use Agreement (DUA) protocols to grant access to Medicare Part D claims data to external researchers, including commercial entities. As CMS notes in the proposed rule, prior research by non-government entities using Parts A and B claims data has had significant positive impact on the financing and delivery of healthcare services. External assessments of the Part D benefit will likely lead to similar improvements.

There is a growing set of research questions that may be answerable by claims data, such as those identified in the recent Institute of Medicine (IOM) reports on medication errors and drug safety[1], and a need for the continued evolution of quality and outcomes research. The IOM reports clearly define roles for all healthcare industry stakeholders in making improvements;

[1] Institute of Medicine. *The Future of Drug Safety: Promoting and Protecting the Health of the Public.* 2006; Institute of Medicine. *Preventing Medication Errors.* 2006.

however, without access to data, commercial entities will not be equipped to contribute as effectively as possible to these research efforts or to the discourse on public policymaking. Constraints on the use of claims data, consistent with the research use provisions of HIPAA, should ensure against inappropriate uses of the data.

To support CMS' commitment to value-driven healthcare, external researchers will need continued access to all Medicare claims data. Medicare – and the Part D benefit specifically – is such an important component of the U.S. healthcare system that broad availability of claims data is crucial to a better understanding and evaluation of the program.

Applicability
There is nothing in the proposed rule that would make HIPAA privacy standards not applicable to the Department of Health and Human Services. Consequently, nothing prohibits CMS from sharing de-identified data with a broad set of users.

Conclusion
Avalere Health commends CMS in its effort to work collaboratively with other government agencies, external researchers, and other stakeholders throughout the development and implementation of the Medicare Part D benefit. We appreciate the opportunity to comment on CMS' proposed rule on the use of Medicare Part D claims data and we look forward to continuing to work with CMS on this important initiative. Please feel free to contact me directly at (202) 207-3675 with any questions or if you need additional information on our comments.

Sincerely,

Valerie Barton

Valerie Barton
Director,
Data Analytics Practice

Submitter : **Pam Dixon** **Date: 12/14/2006**

Organization : **World Privacy Forum**

Category : **Other**

Issue Areas/Comments

GENERAL

GENERAL

Our comments are being filed as an attached document of 11 pages, please see attachment

WPF_comments_CMS4119Pfs.doc

CMS-4119-P-42-Attach-1.DOC

WORLD **PRIVACY** FORUM

Comments of the World Privacy Forum

On

Proposed Centers for Medicare & Medicaid Services rule, Medicare Program; Medicare Part D Data (CMS-4119-P)

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

December 14, 2006

VIA overnight mail and electronic submission

Re: Proposed rule, Medicare Program; Medicare Part D Data (CMS-4119-P)

This is a comment on the proposed rule (file code CMS–4119– P) by the Centers for Medicare & Medicaid Services that would allow the Secretary of Health and Human Services to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. The proposal appears in 71 Federal Register 61445 (October 18, 2006).

The World Privacy Forum is a non-profit, non-partisan public interest research organization. It focuses on in-depth research and analysis of privacy topics. See <http://www.worldprivacyforum.org>. Our concerns about the proposed rule relate exclusively to the effect of the proposal on the privacy rights and interests of plan beneficiaries. We offer no comment on the effect of the proposal on the interests of providers, plans, or sponsors.

I. Background

The background section for the proposed rule explains that the purpose of the rule is to resolve what CMS calls the "statutory ambiguity" involving the limit found in Section 1860D-15 of the Social Security Act (42 U.S.C. § 1395w–115). The key provision of the Act states:

> (f) DISCLOSURE OF INFORMATION.—
> (2) 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.

Congress expressly placed a restriction on the use of Part D information. What the proposed rule attempts to do, and in a very unconvincing way, is to read these words out of the Act entirely. The effect of the proposed rule is to ignore the limitation on data use and disclosure that Congress placed in the legislation. Instead, CMS is attempting to find a justification for avoiding the restriction because CMS considers that its priorities outweigh the congressional direction. Indeed, CMS proposes a rule that will allow the disclosure of information to hundreds of institutions and tens of thousands of individuals notwithstanding the contrary congressional direction.

The weakness of the CMS argument is underscored by the reference (on page 61447) to a press release issued by the House Ways and Means Committee on the day that the legislation was signed into law by the President. The reference is a weak one, because a committee press release issued long after the legislation finally cleared the Congress has no weight as legislative history. Even if the release were entitled to any weight, the vague statement quoted in the proposed rule does not support the interpretation that CMS places on it. Nothing in the quoted words suggests in any way that the privacy interests of Part D recipients should be ignored.

The proposed rule violates basic principles of statutory construction that require that all words in a statute be given meaning and effect. If there is a conflict or inconsistency between different sections of a law, an agency is obliged to make a greater effort to try to reconcile and not ignore those sections. CMS has made no attempt to do so. It has not explained how it might accomplish other functions in whole or in part by proposing a way to use Part D information without personal identifiers, with partially de-identified information, with encrypted information, or though the use of other privacy protective techniques that allow some use of information while masking the identities of data subjects. Any of these techniques would allow other functions to be completed in some manner while acknowledging the clear congressional purpose of limiting the spread of *identifiable* information.

The proposed rule is entitled to no interpretative deference because of CMS' failure to give any meaning to the words of the law or to explain alternatives. Until CMS goes through the steps of explaining all alternatives to ignoring the congressional direction, it has not sustained its burden of justifying the outcome that it seeks. If CMS cannot reconcile the different sections of the law, we recommend that it return to the Congress and seek clarification of the law.

II. Information to be Collected

The underlying argument in the proposed rule is that CMS could, if it chose to, collect the same information under other provisions of the Act that do not include the restriction on data use. The next step in CMS's argument is that requiring sponsors to submit claims information twice would be duplicative. Therefore, CMS can collect the information once and ignore the restriction

on use. This reasoning is faulty because it does not give any weight to the restrictive language. While we do not propose duplicative submission as a practical alternative, we do not believe that even duplicative submission would justify the proposed rule. CMS cannot do indirectly precisely what the statute prohibits CMS from doing directly.

We repeat that CMS has not justified the proposed rule by considering alternatives that would give at least some weight to the express congressional restrictions on use of Part D information. CMS has not considered the possibility of carrying out other functions in whole or in part using Part D information without personal identifiers, with partially de-identified information, with encrypted information, or though the use of other privacy protective techniques that allow use of information while masking the identities of data subjects.

III. Purpose of CMS Collecting Information

The discussion in the proposed rule explaining what CMS wants to do with the information is fatally flawed because no consideration is given to alternatives that would reflect rather than ignore the data use restrictions in the law. All of the activities that CMS wants to carry out can be accomplished in some fashion while complying with the data use restriction. While obeying the restrictions might not allow for full implementation of all desired activities, CMS could still fulfill some or most of its objectives by using Part D information without personal identifiers, with partially de-identified information, with encrypted information, or though the use of other privacy protective techniques that allow use of information while masking the identities of data subjects.

The thinness of the argument here is underscored by the argument that CMS needs to ignore data restrictions in law in order to make legislative proposals to Congress. Agencies throughout the federal government operate daily under a wide variety of statutory data restrictions, yet they seem fully able to propose new legislation notwithstanding those restrictions. CMS' argument about legislative proposals hints at desperation.

In this section on page 61448, CMS requests "comments on whether there should be any limitations on data when shared for purposes other than fulfilling CMS's responsibility to administer the Part D program." We find this request particularly troubling. Does CMS also propose to ignore the data disclosure limitation in the Privacy Act of 1974 that prevents the use of data collected for one purpose from being used for an incompatible purpose? Will CMS ignore restrictions in the substance abuse rules (42 CFR Part 2) too? How far does CMS want to go in sharing Part D data for other purposes? The proposed rule suggests that CMS can ignore legal restrictions that it finds inconvenient. We disagree, and we think that CMS's failure to acknowledge other legal restrictions in the proposed rule and to indicate how it plans to comply with these other restrictions is a major flaw.

The proposed rule begins by seeking to ignore a statutory restriction on data use in order to fulfill statutory purposes related to Part D. While we do not agree with the proposed CMS rule or justification, we acknowledge that reconciling different parts of the law presents a challenge. However, the suggestion that, notwithstanding the express restrictions, CMS nevertheless has the authority to share the data for wholly unrelated activities only serves to undermine the bona fides

of the proposed rule. Does CMS plan to turn patient records over to law enforcement to begin investigations of wholly unrelated crimes? Will CMS turn over prescription information to pharmaceutical manufacturers who want to market their products to patients? Does CMS recognize any limitation on its authority to share patient information? The breadth of the request for comments is even more troubling than the rest of the proposed rule.

IV. Sharing Data with Entities Outside of CMS

In this section – (Proposed Sec. 423.505(f)(5)) -- the proposed rule states (page 61452):

> Given these necessities, we propose to allow broad access for other agencies to our Part D claims data linked to our other claims data files. Other agencies, including the agencies listed above, would enter into a data use agreement, similar to what is used today (and described in greater detail in section II.C.2). This would allow the sharing of event level cost data, however, through a data use agreement we would protect confidentiality of beneficiary information and ensure that the use of Part D claims data serves a legitimate research purpose. We would also ensure that any system of records with respect to claims data is updated to reflect the most current uses of such data. We request comments on this proposed rule that would help us in our efforts to improve knowledge relevant to the public health.
>
> Specifically, we request guidance on how we can best serve the needs of other agencies through the sharing of information it collects under section 1860D–12(b)(3)(D) of the Act while at the same addressing the legitimate concerns of the public and of Part D plans that we appropriately guard against the potential misuse of data in ways that would undermine protections put in place to ensure confidentiality of beneficiary information, and the nondisclosure of proprietary data submitted by Part D plans.

1. We object to the use of the word *necessities* in the first quoted paragraph. Whether or not it would be desirable to undertake the activities discussed in the proposed rule, the statement that these activities are *necessities* goes far beyond anything demonstrated in the predicate to the paragraph. Activities that seek to use data restricted by law are not necessary. Activities that CMS would like to conduct are not necessary.

CMS continues to ignore the statute, first by claiming authority to use data subject to restriction, and now by claiming authority to share data widely throughout the federal government and beyond. Anything that CMS finds convenient or desirable now seems to be a *necessity*. If there is any limitation on the ability of CMS to share confidential patient information with anyone – and we believe that there are several statutory limitations – it is not reflected in this proposed rule.

We once again ask CMS to give effect to the data restrictions that Congress has expressly included in the law.

2. It is impossible to assess the intent of CMS without having the ability to review the system of record notice for the data collected under Part D. Only the system of record notice will explain in

sufficient detail just how far CMS intends to go in sharing patient data. We will not know, for example, if CMS plans to share data with pharmaceutical manufacturers for marketing activities without seeing the routine uses for the system of records.

Publishing this proposed rule without the accompanying system of records notice is a fatal flaw. CMS has only disclosed some of its plans. However, CMS has not told the public how it will accommodate the data use and disclosure restrictions imposed by the Privacy Act of 1974. That information is essential to evaluating the proposed rule. The failure to publish a system of records notice along with the proposed rule makes it impossible for a commenter to fairly assess the full scope and legality proposed rule. A system of records notice is an integral part of any personal data use activity contemplated by a federal agency. We recommend that CMS republish the proposed rule along with all relevant system of records notices that will cover the data in question.

3. In response to the request for guidance for data sharing, we suggest that if any data sharing can be lawfully done under the Part D data restrictions, CMS should allow data sharing of Part D information without personal identifiers, with partially de-identified information, with encrypted information, or though the use of other privacy protective techniques that allow use of information while masking the identities of data subjects. The many techniques for masking the identifiability of data that have been developed by statisticians should be mandated for Part D data if the data is to be shared at all. Aggressive use of identifier protection methods will allow most of the objectives of sharing to be accomplished.

4. Along these lines, we take note of the statement that "[t]his would allow the sharing of event level cost data, however, through a data use agreement we would protect confidentiality of beneficiary information." This statement suggests a fundamental misunderstanding of privacy. Sharing of data is a breach of confidentiality. It exposes the data to new eyes, to additional security breaches, and to new threats to privacy. Undertaking data sharing though a data use agreement can mitigate the threat to privacy, but it does not eliminate it.

We support the use of data use agreements when data must be shared and when it is lawful to share data. However, CMS should realize that the sharing of data – even with the admonition that the data should not be further disclosed – still directly undermines the privacy of data subjects. We acknowledge that data sharing is sometimes justifiable, but that does not mean that privacy interests are unaffected by the sharing. CMS's case for data sharing would be enhanced if it could manage to demonstrate a greater understanding of and sensitivity to privacy.

> The proposed rule provides:
>
> See our Agreement for Use of Centers for Medicare and Medicaid Services Data Containing Individual Specific Information at http://www.resdac.umn.edu/docs/CMS-R-02352-v2-locked.doc. In addition, we would ensure that our system of records for claims data would permit these usages of the data. We request 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. We also ask for comments on whether we should

> consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.

1. We were surprised to find that the standard agreement for use of CMS data does not include a requirement that the recipient obtain a certification of confidentiality for all identifiable CMS data covered by the agreement or other data within the scope of the research project. In general, certificates of confidentiality authorize researchers to resist compulsory legal demands (e.g., subpoenas and court orders) for identifiable research information about individuals. By providing a defense against compelled disclosure, certificates provide a defense against legal obligations to disclose records to law enforcement agencies, private litigants, and others who may have an interest in the records for different purposes. One statute that establishes a certificate program is 42 U.S.C. § 241. Other statutory certificate of confidentiality programs may also be available to CMS data users.

2. A certificate provides an extra layer of protection for the privacy interest of data subjects that is not readily available through other means. We recommend that all researchers, whether in federal agencies or other organizations, who seek identifiable or potentially identifiable data from CMS be required to obtain a certificate of confidentiality or to explain (preferably in a public document) why a certificate is not available.

3. We further recommend that the CMS data use agreement be amended to provide expressly that the data subjects of any data disclosed under the agreement are third party beneficiaries of the agreement. By so providing, the agreement will enhance the accountability of the researcher and may allow an aggrieved data subject to seek relief if his or her data is misused or improperly disclosed. The criminal penalties cited in paragraph 15 of the standard CMS data use agreement are useful but not sufficient. A data spill or other action by a researcher that harms a data subject may or may not rise to the level of criminality. Further, the willingness of the government to pursue criminal penalties even when available or appropriate is always uncertain. Providing for the possibility of a private remedy (if available under the law of the jurisdiction in question) enhances the relief that a data subject can pursue without the need for the approval of a government prosecutor.

4. In offering these comments on the CMS data use agreement, we want to note that we have not fully reviewed the agreement. Our comments here should not be construed as approval of the other provisions. It would be useful for CMS to independently seek public comment on its data use agreement.

V. Regulatory Impact Statement

The proposed rule does not include a regulatory impact assessment. The justification states:

> Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and

> safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Neither plan sponsors nor pharmacies are required to perform any new task or purchase any new equipment or increase their labor force. This proposed rule does not reach the economic threshold and thus is not considered a major rule.

We believe that the judgment that the proposed rule is not economically significant is wrong. Even if it is true that no new tasks, equipment costs, or labor costs are imposed on sponsors or pharmacies, the costs and benefits of the proposed rule far exceed the $100 million threshold and require a regulatory impact analysis. CMS reached its conclusion about costs and benefits without undertaking a fair or comprehensive assessment of costs and benefits from the proposed rule.

The proposed rule will result in the use and sharing of sensitive health information about millions of Americans. The value of the information on millions of drug recipients should have been estimated as a starting point for the analysis because it is a proxy for the costs imposed on data subjects. Personal information has a value in the marketplace, and it is possible to determine a value using this crude market measure. We can begin the exercise by offering an example of the type of analysis that CMS should have undertaken.

Data and list brokers rent information about individuals by health condition.[1] If we assume that there are an average of five data elements about the prescription drugs taken by 10 million individuals, then there are 50 million data elements. Mailing lists often rent for 10 cents a name. A list that reveals the prescription drug purchases, even with nothing more than name, address, and prescription drug, would be far more valuable. However, even the ten cents a name value produces a value of $5 million dollars, and the list might rent multiple times a year. This represents a good percentage of the $100 million threshold that would require a regulatory analysis. Adding in the value of information on the prescribing habits of physicians will further increase the total value of the information in the database. You can measure that value by looking at the profit statements of the commercial companies that traffic in physician data. Overall, we estimate that just the commercial value of the data in the Part D database exceeds the threshold. The marketplace value of the information is one measure of the economically significant effects of the proposed rule.

However, that only begins the economic analysis. A regulatory impact analysis must also consider the value of costs and benefits that cannot be measured in monetary units. The privacy consequences of the data sharing activities that the proposed rule would allow must also be assessed. It is difficult to put a dollar value on privacy, but the widespread sharing of data that CMS proposes will affect the privacy of every individual in the database. We know that many individuals value privacy highly. Some value their privacy so highly that they pay for health care costs out-of-pocket rather than report their treatments to insurers. This is one limited measure of the value of health privacy, and we believe that it is susceptible to measurement.

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[1] For example, as of December 12, 2006, Walter Karl offered an "Ailment Sufferers Database" (list ID 108171) of 3,129,351 individuals with ailments such as asthma, diabetes, frequent headaches, Parkinson's Disease, and a host of other ailments. For more information, see <www.walterkarl.com >. Also, see Appendix A attached to these comments to see a screen shot of the data card on this list, current as of December 12, 2006.

We can create a broader measure with some reasonable assumptions. If we assume that Part D beneficiaries value their privacy at an average of only ten dollars a year, the value of privacy will exceed the threshold if there are only 10 million beneficiaries. If there are twenty million beneficiaries, we reach the threshold if privacy is valued at only five dollars a year.

Considering the risk that data sharing will increase the threat of a data breach offers another measure. Assume that there is a five percent chance of a data breach as a result of the significant amounts of data sharing that the proposed rule contemplates. Assume further that a data breach will require the purchase of credit monitoring for the data breach subjects (a common remedy paid for by the person responsible for the breach). Credit monitoring for one year for ten million individuals would cost several hundred million dollars. If the risk is five percent, this adds another possible ten or twenty million dollars in costs.

We can continue this preliminary assessment by considering the value of the activities for which the data is proposed to be shared. These activities involve costs that need to be assessed. The envisioned data transfers will result in the expenditure of government and other funds, and these are costs that must be considered. The costs may be outweighed by the resulting benefits. We think that CMS is in a far better position to estimate the potential costs and benefits of the research and administrative activities described in the proposed rule.

The overall point should be clear: CMS did not make any attempt to identify and assess all of the costs and benefits that may result from the proposed data sharing. We believe that it is crucial that privacy consequences of any proposed use or disclosure of personal information be included in any regulatory analysis. The difficulty of monetizing privacy costs should not be a barrier to attempting to place an appropriate dollar value for regulatory purposes. Failure to consider privacy leaves program beneficiaries to bear the costs and consequences of data sharing without those costs and consequences being considered to determine if the proposed activities are justifiable from an economic perspective.

CMS's failure to perform a regulatory analysis is a fatal flaw for the proposed rule. We believe that CMS must perform an analysis and republish the rule again for public comment.

VI. Other issues

A. HIPAA

HIPAA applies to Part D drug plans. However, the proposed rule does not explain why the Department has chosen to deny the applicability of HIPAA to CMS Part D activities when HIPAA applies to CMS activities for Parts A & B of Medicare. The proposed rule has only one brief mention of HIPAA, and that statement does not explain why HIPAA does not apply. An explanation would not only have been helpful, but it would have exposed the more precarious state of the privacy of Part D information in the possession of CMS.

Further, we believe that regardless of the technical applicability of HIPAA to Part D, the Department has made a poor choice in not applying HIPAA to CMS's Part D data activities. The

Department has the administrative capability to extend HIPAA to Part D. By having different privacy rules applicable to different parts of Medicare, the Department is making it more complex, difficult, and confusing for Medicare beneficiaries to understand and exercise their privacy rights. Another effect is a likely increase in confusion within CMS as employees struggle with patient data subject to differing privacy regimes.

We also observe that protections of the HIPAA security rule will not apply, and that this too raises costs and undermine patient protections. A recent GAO report found serious problems with security controls at CMS. See *Information Security: The Centers for Medicare & Medicaid Services Needs to Improve Controls over Key Communication Network* (GAO-06-750) (Oct. 3, 2006).

More broadly, the Department's failure to apply HIPAA makes CMS's Part D operations the second major health data intensive activity within the Department of Health and Human Services to which the Department has avoided application of HIPAA. The other activity is treatment programs of the National Institutes of Health. While both conclusions may be technically correct under the currently defined scope of HIPAA, it would be simple for the Department to reach a different, fairer, and better result by adjusting the HIPAA rules to include these activities. By evading the application of HIPAA to these two health data intensive activities, the Department undermines public confidence in the operation of these two health programs and raises question whether the Department truly values the privacy and security protections of HIPAA. The protections of HIPAA should be available to patients at NIH and to beneficiaries of Part D whose data is in the possession of CMS.

B. Privacy Impact Assessment

The data activities that CMS proposes require the completion of a privacy impact assessment (PIA). OMB guidance on the E-Government Act of 2002 says that an agency must undertake a PIA "where a system change creates new privacy risks." There is no doubt that the proposed rule creates new privacy risks through the widespread sharing of data about drug recipients under Part D.

We see no evidence that CMS has conducted or plans to conduct a PIA. We believe that a PIA is required before the proposed rule can be implemented. We ask that CMS prepare a PIA, publish the PIA for public comment, and consider the comments before proceeding with the proposed rule.

C. Shortcomings of the Data

We do not have a clear understanding of the full scope of the data being collected. However, we can see some major shortcomings that may make the data far less useful than the proposed rule suggests for the many purposes that CMS envisions. We think that the data will likely turn out to be significantly incomplete and may not provide results that are useful or reliable. This in turn suggests that the conclusions that CMS wants to derive from the data may not be valid. If so, then there may well be no good reason to risk the privacy interests of beneficiaries in pursuit of flawed research and analysis.

Data may be missing from the database when drugs are paid for by wholly private health plans. Information on prescription drug use and purchase may also be missing for those who fall within the so-called donut hole in Part D. The proposed rule fails to recognize these potential shortcomings or to acknowledge that the data gaps will make it more difficult to achieve the benefits that the proposed rule contemplates. Further data problems may arise if the Part D program is subject to fraud or medical identity theft. Given the current rate of fraud in other CMS programs, then it stands to reason that Part D will also suffer from similar fraud issues, which will have a cumulative impact on data quality.

If flaws and gaps in the data make it impossible to reach valid conclusions, then the entire exercise may be pointless. Until CMS explains in more detail what data will be collected, what data won't be available, and what data may be useless because of fraud or other flaws, it is impossible to assess the value of the uses to which CMS expects to put the data.

Potential problems with the data are extremely important. CMS's basic argument that it must ignore the congressional data restrictions in order to find facts and reach conclusions about other matters. If the data's flaws are too great to achieve CMS's goals, then the purported justification for ignoring the data restrictions is undermined, perhaps fatally.

VII. Conclusion

CMS needs to do more to explain its plans for greater use of sensitive patient data and all of the possible alternatives to those plans before it can fairly ask for public comment on the proposed rule. Further, the public needs to see a draft Privacy Act system of records notice, including proposed routine uses, a Privacy Impact Assessment, and a Regulatory Impact Statement. Seeking public comment on the proposed rule without offering more information to the public is simply inappropriate.

We ask that CMS cancel the proposed rule, provide the additional information needed, and then publish another rule for comment.

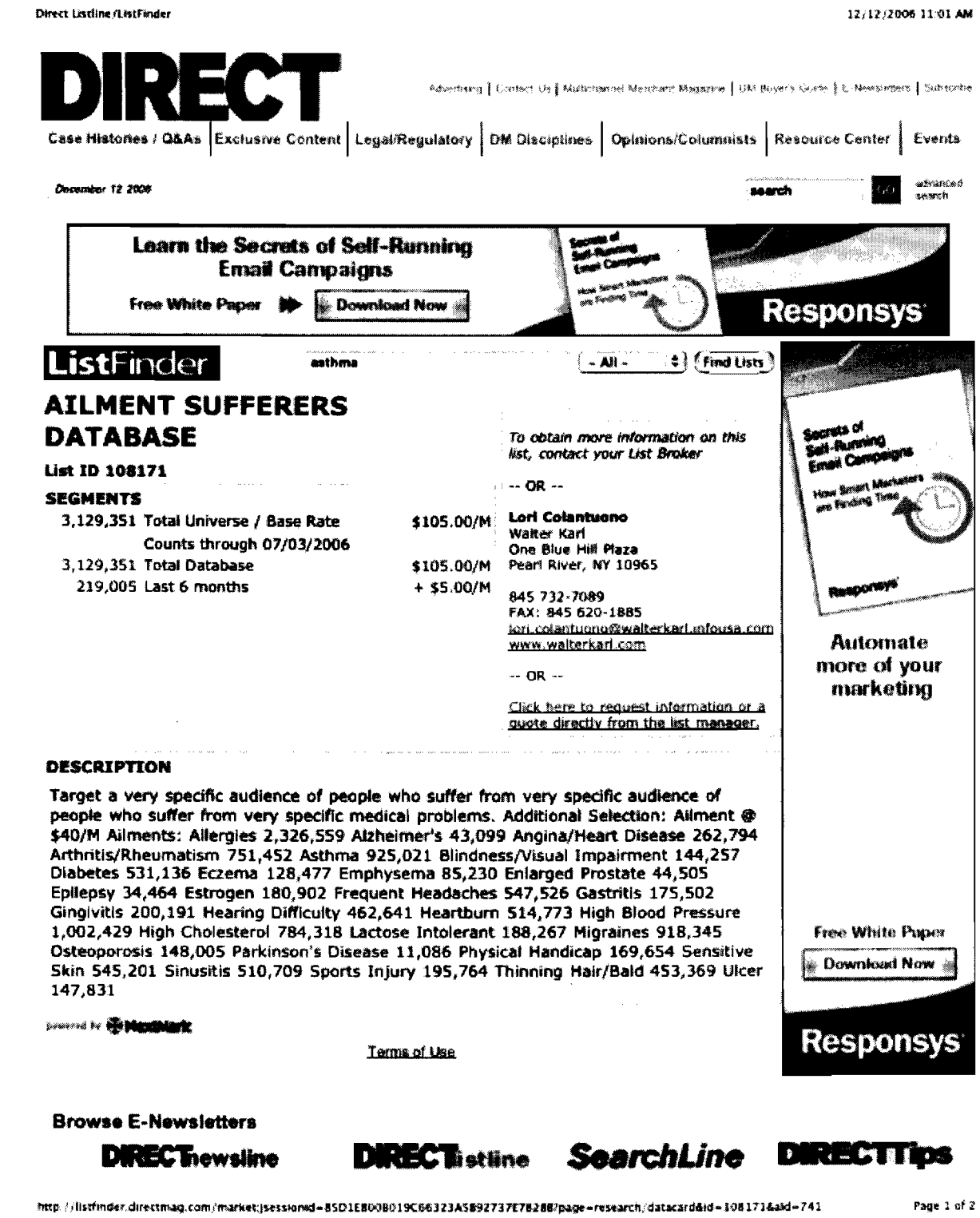
We thank you for the opportunity to submit these comments.

Pam Dixon

Executive Director,
World Privacy Forum

Attachment: Appendix A

Appendix A



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SEGMENTS

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	Counts through 07/03/2006	
3,129,351	Total Database	$105.00/M
219,005	Last 6 months	+ $5.00/M

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