Submitter : **Ms. Beth Levine** **Date: 12/18/2006**

Organization : **Pfizer Inc**

Category : **Drug Industry**

Issue Areas/Comments

Applicability

Applicability

See attached document.

Beneficiary Access of Part D Data

Beneficiary Access of Part D Data

See attached document.

GENERAL

GENERAL

See attached document.

Information to be Collected

Information to be Collected

See attached document.

Limitations

Limitations

See attached document.

Purpose of CMS Collecting Information

Purpose of CMS Collecting Information

See attached document.

Sharing Data with Entities Outside of CMS

Sharing Data with Entities Outside of CMS

See attached document.

CMS-4119-P-94-Attach-1.PDF

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December 18, 2006

Leslie Norwalk, Esq.
Acting Administrator
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

Re: **CMS–4119–P; Medicare Program; Medicare Part D Data**

Dear Ms. Norwalk:

I am writing on behalf of Pfizer Inc, a research-based, global pharmaceutical company dedicated to the discovery and development of innovative medicines and treatments that improve the quality of life of people around the world. We are pleased to comment on the Proposed Rule recently published by the Centers for Medicare & Medicaid Services regarding the use of claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions (the "Proposed Rule").[1]

I. SUMMARY

As described below, we generally support CMS's proposal to collect and use Part D data for purposes other than payment, but believe that research conducted utilizing these data must be methodologically sound and promote high quality health care, that dissemination of such

information should be closely monitored to ensure that users of the information recognize its limitations, and that beneficiary interests should be fully protected. Specifically, we make the following recommendations:

- All qualified researchers, including pharmaceutical companies, should have equal access to Part D and other Medicare claims data;

  Rather than precluding use of the data for certain types of research, CMS would be better served by focusing on assuring researcher quality and integrity, and on ensuring that researchers adopt sound methodologies in conducting their analyses;

- A mechanism for ensuring rigorous research would be to create study panels consisting of qualified external stakeholder experts that would review, in an efficient and reasonable time frame, research protocols before Medicare data is released to an entity;

- Data users should agree to make every reasonable attempt to subject results to peer review; and

  CMS (and other government agencies) should clarify how they intend to use the results of Part D claims data analyses, and allow for public review and comment on those proposed uses before implementation.

We appreciate this opportunity to comment on the Proposed Rule and look forward to working with CMS to achieve these objectives.

II. INTRODUCTION

A. Background

We bring to the discussion of this important issue extensive institutional experience in analyzing de-identified prescription drug and medical claims data to evaluate clinical and cost outcomes both in the United States and abroad. We have one of the largest medical outcomes research groups in the industry, with solid expertise in evaluating utilization and costs of pharmaceuticals, the impact of treatment adherence, and related issues. Pfizer's outcomes research group has clinical, epidemiological, economic, statistical, pharmacy, and psychometric experts who design, conduct, and publish study results on health care outcomes from most of the publicly available and private claims databases. This department partners with major academic institutions, some pharmacy benefit management companies (PBMs), managed care organizations, and contract research organizations to conduct prospective outcomes research.

In addition, we have substantial expertise in drug safety surveillance and reporting. For example, our Safety and Risk Management group is composed of 600 professionals, approximately 300 of whom are dedicated to safety surveillance and reporting. These highly trained individuals conduct minute reviews of adverse event reports to help assure prompt identification of potential safety issues.

In sum, Pfizer has specific and substantial experience and expertise working with and understanding the merits and limitations of analyzing large claims data sets. This expertise is widely reflected in the peer-reviewed literature.[2]

B. Our Interests

Pfizer strongly agrees with CMS that the Part D claims data set has significant potential to support high quality research that will ultimately inure to the benefit of patients. From Pfizer's perspective, there are a number of important public health benefits associated with the appropriate collection and research use of these data:

1. Efficiency

The most costly aspect of conducting clinical trials is often collecting the data. The costs of collecting data can limit the amount of the information that can be generated for analysis. The availability of the Part D claims database may increase efficiency by reducing research costs while still giving researchers access to an extensive dataset. Government agencies have recognized the efficiency benefits of making administrative databases available for research purposes. For example, the Agency for Health Care Policy and Research (the predecessor to the Agency for Healthcare Research and Quality) has provided Medicare Parts A and B data to funded grantees precisely because of the efficiency of using existing data.[3]

2. Generalizability and Bias

Currently, pharmaceutical manufacturers and other researchers must use private databases to analyze drug utilization by seniors. These private databases may be susceptible to limitations, including but not limited to population biases. Population bias in private databases is a particular concern when seeking to analyze drug utilization by older patients. Most of these databases do not include populations over the age of 65. Those that include such populations typically do so on a limited basis. As a result, these private databases can have limited utility in supporting

statistically valid analyses generalizable to elderly populations. The CMS proposal would significantly improve the research opportunities presently offered by private databases by providing researchers with access to an extensive database that includes both those over the age of 65 and a younger disabled population.

3. Uses

Part D claims data could be responsibly used in a variety of ways to promote good science and impact public health. For example, such data could be used to support post-marketing surveillance of drugs, help to accelerate pharmaceutical research and development, and enhance outcomes research. This population-based database of elderly medical claims is an important supplement to other currently available databases which are heavily focused on employed and insured populations and their families.

The Part D claims data could become an important catalyst for clinical research. These data are an efficient way to generate hypotheses that focus on clinical areas requiring further study. Linking the Part D data to Parts A and B data could be extremely valuable. Hospitalization rates might be analyzed in conjunction with Part D claims data to develop hypotheses about effective and cost-effective drug therapies are in treating certain populations.[4] Linked Medicare data could also be utilized to develop or focus hypotheses about heterogeneity of treatment effects in the elderly population.

Access to Medicare claims data and the ability to conduct investigations in large numbers of patients provides opportunities to improve the drug research development process. The appropriate aggregation and linkage of de-identified Medicare Parts A, B and D data would allow researchers to explore possible safety signals for a product or a class of products, a disease,

and/or drug issues related to co-morbidities or drug-drug interactions. While causation can never be determined from a retrospective review of a claims database, even one as large as the Medicare claims database, research that leverages all available Parts A, B and D claims data could potentially contribute to an understanding about why some patients may switch from/to particular medicines and help scientists understand why some patient populations respond to certain classes of drugs and others do not (i.e., heterogeneity of treatment effects). These types of studies may contribute to the pharmaceutical research industry's ability to focus on subpopulations, to design more specific studies that can tell us how genetics or physiology affect response to treatment. Conducting studies with these data prior to designing clinical trials can increase the efficiency of the costly trials process, as the information can be used to help focus on the appropriate subgroups of patients or provide information on the likelihood of identifying eligible populations for recruitment into trials.

III. COMMENTS ON DRAFT PROVISIONS OF THE RULE

A. Purpose of CMS Collecting Information

CMS is proposing to use Part D data for a variety of general purposes, including reporting operational statistics about Part D to Congress and the public, conducting evaluations of the Medicare Program; making legislative proposals on CMS-administered programs, and conducting demonstrations projects.[5]

The Proposed Rule lists a number of examples of the types of analyses CMS could potentially conduct using these integrated data and those illustrations are very useful. Nevertheless, we ask that CMS further clarify how it intends to use the results of Part D claims data analyses. As noted, claims data analyses are susceptible to a number of limitations, even

when the dataset is as large as the Part D claims dataset. To the extent that CMS or any other entity is proposing to use these data to make policy decisions, the methodologies and their outputs should be subject to public review and discussion. This should include, where appropriate, open and transparent procedures for reviewing the study design and analyses.

1. Limitations of Administrative Claims Databases

Claims data are undoubtedly useful to investigate a number of health care issues, including quality performance, adherence, and the impact of cost-sharing. However, CMS, other agencies, and external researchers should have a clear appreciation of the limitations of these data. We wish to ensure that researchers (and reviewers) do not assume that database size correlates positively with the quality of the data therein. In other words, the fact that a database contains a lot of data does not necessarily mean that it is of (uniformly) high quality or useful for all purposes. For example, Medicare claims data may have the capacity to provide insights into the safety and effectiveness profiles of drugs in a population much larger than could ever be studied in a clinical trial. However, the results from these analyses cannot be interpreted in the same context as results from blinded clinical trials specifically designed to prospectively address hypotheses and assess causality. Researchers and policymakers should not impute more reliability to the results of analyses of the Part D claims database simply because they are derived from such a large database.

Researchers should also scrupulously distinguish between clinically significant and statistically significant results. With a large sample size such as the Medicare Part D population, results will almost always be statistically significant. However, this may not always signify that they are clinically significant.

2. Methodological Limitations of Administrative Claims Databases

The use of observational data sets like the Medicare claims data, while valuable, has methodological limitations because these data were collected for reasons other than research. As already noted, causality cannot be assessed with secondary data – at best, only associations/relationships may be suggested. Experience suggests that secondary data is most useful for hypothesis generation, refocusing research questions and testing methods and models. In limited cases, it can support hypothesis testing. Other methodological limitations can include the following:

Lack of clinical detail in the data (e.g., lack of laboratory and radiology results);
Lack of outcome measures (e.g., no references or limited references to disease resolution, reduction in severity, reduction in risk, improvement in function, quality of life, patient satisfaction, patient preference);
Lack of clinical measures (e.g., omitted blood pressure, weight);

- Must assume that drug utilization, laboratory results, and test results can be used as proxies for a diagnosis (e.g., drawing inferences that patients on antidepressants have depression);
Must assume severity or acuity based on combinations of claims and use of scoring algorithms (e.g., using inductive reasoning to evaluate ICD-9 codes, DRGs and CPT codes, which do not necessarily provide reliable indications of severity);

- Lack of information on service use outside of the system (e.g., no or sporadic references to OTC drugs, nutritional supplements, herbals, and uses for which claims were not submitted);
- Misclassification and coding issues which can result in a fatally flawed study; and
- Missing and out-of-range data resulting in deletion of cases which introduces bias.

All government agencies, as well as external researchers, should have a realistic understanding of these limitations in order to ensure the most appropriate use of these data sets.

B. Sharing Data with Entities Outside of CMS

The Proposed Rule states that, "[i]n addition to collecting claims data for use in administering the Medicare Part D program ... CMS also believes that it is in the interest of public health to share some of the information collected under that authority with entities outside of CMS."[6] The agency proposes sharing this claims information with other government agencies (including oversight agencies) and external researchers. For example, CMS cites other government agencies such as the National Institutes of Health, the Food and Drug Administration, and AHRQ, and external researchers such as university-based researchers.

With respect to the use of the database by government agencies, CMS requests guidance on how it can "best serve the needs of other agencies through sharing of information it collects ... while at the same [time] 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."[7]

We agree with CMS that other government agencies' use of this data should be appropriately regulated and we request that the agency clarify how other government entities may use the results of these analyses. We also suggest that CMS invite public comment on these potential uses. It is imperative that CMS and other agencies ensure an open and transparent process for conducting research using linked Medicare claims data and applying their findings to important questions of public policy. In general, we believe that CMS and other government entities should **not** be treated any differently than external researchers for purposes of sharing these data. All agencies should generally be required to comply with the peer review and other process standards described below for external researchers.

With respect to use of linked Medicare claims data by external researchers, CMS requests comments on: 1) the proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to the public health; and (2) whether the agency should consider additional regulatory limitations for external researchers beyond its existing data use agreement protocols in order to guard against the potential misuse of data.[8]

Our comments on these and related issues are as follows:

a. All Qualified External Researchers Should Have Access to Data

Pfizer strongly believes that Part D claims data should be directly accessible by all qualified external researchers, including commercial entities such as pharmaceutical manufacturers, insurance companies, and pharmacy benefit management companies. CMS should not arbitrarily exclude entities requesting access to these data, provided such entities can demonstrate that they are qualified to perform the research and have agreed to abide by CMS's requirements for using the data. As you are aware, the Administrative Procedure Act prohibits

government agencies from acting in a manner that is "arbitrary and capricious," which the courts have interpreted as requiring agency action to have a rational basis for taking action.[9] CMS should make Part D claims data (including Part D data linked to Parts A and B data) broadly available, because there is no rational basis for limiting access to them.

In addition, offering only a limited number of researchers access to this publicly-generated data could lead to fundamentally distorted research results. For example, offering the data only to academic institutions or some other subset of external entities would have the practical effect of distorting the pool of potential researchers, the types of research that might be conducted, and, potentially, the conclusions that could be legitimately drawn from that research. If, for example, pharmaceutical manufacturers were not permitted access to the data, they would be unable to test the hypotheses and conclusions – favorable or unfavorable – advanced by those with access. For these reasons, all researchers, including manufacturers and other non-academic entities, should have direct access to the raw datasets. This would be broadly consistent with the approach adopted by FDA when it uses a private database for post-marketing studies (e.g., safety). The FDA makes these databases available for industry representatives so that they can replicate the research themselves.

To the extent that these data may be useful in the context of post-marketing surveillance, there are compelling reasons to believe that manufacturers can conduct research with these new data as effectively as the FDA. Both the FDA and manufacturers have very strong incentives to perform in-depth, comprehensive research in this area. However, the broad array of treatments in health care presents a challenge to the resource capacity of a single entity, such as the FDA, to look across a large number of treatments to investigate safety. For entirely practical reasons, FDA might need to focus its attention, for example, on a few areas of treatment that have high

costs or utilization. In contrast, pharmaceutical manufacturers are strongly motivated to evaluate whatever information may be gleaned about their marketed medicines, whether they are on the FDA's priority list or not.

Finally, sharing these data with a large and diverse group of external researchers can provide valuable insight on trends in patient care and improve the quality of care. CMS has already recognized that external researchers that are currently permitted to analyze Medicare data have contributed to "significant improvements in health."[10] The greater the numbers of qualified researchers who access these data and repeat and validate analyses, the greater the quality of information generated about the relationships between drug utilization and quality health care. As previously indicated, these data cannot support cause and effect determinations, but may be well-suited to generating hypotheses, and helping to identify and focus areas and methods of research. The more widely these data are made available for research, the better the methods for using these data will be refined. Application of different models in the same database tests the consistency in results and indications of trends in results, This, in turn, improves confidence in the findings. For all of these reasons, CMS should permit broad access to these data to allow for research on a wide range of legitimate questions that can expand the evidence base and contribute to improved health care and policy decision-making.

a. No Particular Research Use Should be Excluded

In the Proposed Rule, CMS asks for guidance on whether the agency should consider additional regulatory limitations to guard against the potential misuse of data for "non-research" or "commercial" purposes. CMS should clearly define those types of research uses considered "commercial purposes." In fact, we question the premise that research for "commercial"

purposes might be rationally or usefully distinguished from other kinds of research. For example, comparative effectiveness research (broadly defined to include comparisons of procedures, policies, products, etc.) provides information to policymakers but might also produce an analysis that could be appropriately used to communicate comparative benefits and risks for a particular drug, device, or procedure in a commercial context. This type of research undertaking can represent a win-win for patients – useful research information and useful commercial information that can be directly and concretely applied in the marketplace. The more information that can be developed that empowers physicians and patients to make good decisions about patient treatment, the better. Indeed, it is difficult to understand why such studies should be restricted.

Rather than precluding use of the data for certain types of research, CMS would be better served by focusing on assuring researcher quality and integrity, and on ensuring that researchers adopt sound methodologies in conducting their analyses.

b. Appropriate Processes Should be Implemented to Ensure Rigorous Research

i. *CMS Should Create a Study Panel to Review Research Protocols*

Pfizer recommends that CMS strengthen and improve the transparency of its process for releasing Medicare claims data for research purposes. As already noted, we strongly believe that **all qualified** researchers should have access to Medicare data. Decisions on release of data should be based on the researchers' qualifications, the legitimacy of the research question, and the soundness of the research protocol. We suggest one mechanism for ensuring rigorous research would be to create study panels consisting of qualified external stakeholder experts (similar to the Medicare Coverage Advisory Committee – recently re-chartered as the Medicare

Evidence Development & Coverage Advisory Committee – or an NIH study section), that would review, in an efficient and reasonable time frame, research protocols before Medicare data is released to an entity. What is not desirable is unilateral, internal decision-making by the agency or a sister agency that is not transparent or not based on clear criteria that are known to all parties. The panel (or panels) would evaluate and comment on the proposed research methodology, as the NIH and AHRQ study sections currently do. This would help ensure that research protocols are scientifically sound. In addition, the panel should require researchers, in appropriate circumstances, to secure review and approval of the contemplated study by an institutional review board. Study panel(s) of this kind would help assure methodologically sound study designs and analytical techniques, and that researchers have a clear understanding of the limitations of these data.

ii. *Studies Should Be Appropriately Prioritized Using a Neutral and Transparent Process*

We recommend that the study panel(s) review requests for data on a first-in, first-reviewed basis. The panel could subvert the queue in limited circumstances, e.g., if an urgent patient safety concern or public health emergency is at issue. Further, CMS should publish guidelines for determining how research requests are reviewed, how long they can pend without action, and how declined requests would receive a 'second look' or 'appellate review.'

We suggest that federal government agencies or oversight entities should generally not be given preferential treatment in processing requests for access to the data. These agencies and entities should be required to submit to the same processes as external entities, except, perhaps, in the case of an immediate and paramount public health need for the information. To the extent

that the study panel(s) establishes any standards for prioritizing requests, the development of such standards should also be subject to a public process.

Further, in order to ensure that the agency has sufficient resources to consider all appropriate requests in a timely manner, it may wish to consider implementing a reasonable user-fee system for obtaining access to these data. A reasonable user fee would not unfairly burden legitimate researchers and would help reduce the administrative burden on CMS.

iii. *Data Users Should Agree To Make Reasonable Attempt to Subject Results to Peer Review*

To further the goal of ensuring rigorous research, we recommend that CMS require all users of Medicare claims data to make every reasonable attempt to have their research findings peer-reviewed by identified bodies of experts in their clinical and research areas before they are disseminated. This requirement should apply equally to all data users, whether they represent academic institutions, pharmaceutical companies, federal agencies, or other stakeholders. Dissemination should be broadly defined to include, but not be limited to, publishing the study findings in a peer-reviewed journal (which obviously ensures peer review), and compiling fact sheets, "white papers,"or other reports for distribution to the public either in hard copy or on a website. Further, CMS should proactively address the possibility that research findings that fail peer review will be self-published nevertheless, without addressing the shortcomings identified in the peer review process. Rigorous peer-review is necessary and proper to ensure that expanded access to the Part D claims data yields cogent and reliable research results.

iv. *Data Use Agreements Should be Utilized and Updated*

CMS currently uses data use agreements (DUAs) to outline the conditions under which the agency will distribute Medicare data files. We concur with CMS that DUAs should be required here.[11] However, CMS should update DUA-related documentation based on the recommendations outlined above. For example, CMS should delete language in paragraph seven of its "Criteria for Review of Requests for CMS Research Identifiable Data," which currently states that "CMS will review the source of funding to determine if the requestor is independent of the funding organization. For example, CMS has historically denied data requests from requestors wanting to evaluate the impact of prescription drugs if a pharmaceutical company finances the study."[12] Based on our recommendations above, we recommend deleting this criterion.

Any revised DUA should also include any necessary provisions to fully protect the confidentiality of beneficiary information. In the past, CMS has encrypted Medicare Part A and B data to de-identify patients prior to use of the data in research. We recommend that the same or similar algorithms be applied to the combined Medicare Parts A, B, and D data set to ensure confidentiality. No data user should be provided with patient-identifiable data.

c. Data Should be Timely

Delays in the release of data to other government entities or external researchers may substantially diminish its value. We recognize that there is some time lag inherently associated with claims data because claims are submitted and paid at various times. However, we urge CMS to work aggressively to limit this lag. Time lags, in particular, severely diminish the utility of safety analyses.

C. Beneficiary Access to Part D Data

We understand that CMS may wish to use Part D claims data for the development of personalized beneficiary medication history records, and that comments have been requested on this proposed use of the data. Generally, Pfizer believes that providing greater access to information that will help Medicare beneficiaries better manage their health is of vital importance. We look forward to learning more about CMS's proposals in this area, and ask that CMS utilize a transparent process for developing these ideas, and allow for public comment in the future.

D. Applicability

The Preamble provides that the Proposed Rule does not affect the "applicability of HIPAA to the Department or any other appropriate parties, nor does it affect the applicability of the Privacy Act or the Trade Secrets Act."[13] Notwithstanding this disclaimer, the Proposed Rule provides that CMS will collect and use "drug claims and *related information.*"[14] We request clarification as to the meaning of "related information," insofar as this language suggests CMS may be contemplating using and sharing rebate and other discount and price concession information. We request that CMS confirm that it is not proposing to undermine confidentiality protections currently afforded by law and to clarify specifically that the proposed regulations would not affect the applicability of the Trade Secret Act to pricing data.[15]

E. Limitations

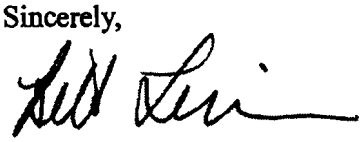
In proposing to expand the use of Part D data for research and other purposes, CMS is relying on a broad interpretation of its existing statutory authority.[16] While the proposed expansion of CMS's authority under 42 U.S.C. § 1395w-112(a)(b)(3)(D) to facilitate review of

Part D claims data seems unexceptional, we do not believe that the agency's authority would support the access and manipulation of other kinds of sensitive data that have independent statutory protection from disclosure, such as confidential manufacturer rebate information. CMS should confirm that it does not intend to use its § 1395w-112(a)(b)(3)(D) authority to disclose these other kinds of data.

IV. CONCLUSION

We appreciate the opportunity to comment on the Proposed Rule, and hope that our comments will contribute usefully to the preparation of the final regulation. Pfizer believes that the availability of Medicare Part D claims data for research use has the potential to dramatically improve health outcomes and reduce overall health care costs. Consequently, we support this initiative and offer our expertise in furthering its development and implementation. Please do not hesitate to contact us if we can be of any assistance or if you require any additional information. We look forward to continuing our dialogue with CMS on these critically important issues.

Sincerely,



Beth Levine

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

[2] *See*, e.g., Goldstein JL, Howard KB, Walton SM, et al. *Clinical Gastroenterology and Hepatology*. 2006;4:1337-1345.

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[3] U.S. DHHS, PHS, AHCPR. "The Feasibility of Linking Research-Related Databases to Federal and Non-Federal Administrative Databases: Report to Congress. " U.S. DHHS Publication, Pub. No. (PHS) 91-003. Office of Science and Data Development, Agency for Health Care Policy and Research. Rockville, MD: public Health Service: April 1991.

[4] *See* 71 Fed. Reg. at 61449 ("For example, it will be important to determine if the provision of the Part D benefit decreases spending under Medicare Parts A and B because patients are more readily able to obtain necessary medications while living in the community, which may help them comply with drug regimens and avoid more expensive inpatient care. Part D data could be used to determine the impact of the Part D benefit on reducing medical complications and as a result reducing costs incurred in other parts of the Medicare Program, for example, by reducing hospitalizations and procedures.").

[5] 71 Fed. Reg. at 61448.

[6] 71 Fed. Reg. at 61451.

[7] 71 Fed. Reg. at 61451.

[8] 71 Fed. Reg. at 61452-53.

[9] *See* 5 U.S.C. § 706(2)(A); *see also* Motor Vehicle Manufacturers Association of the United States, Inc., et al. v. State Farm Mutual Automobile Insurance Co. et al., 463 U.S. 29, at 42-43 (1983) ("...agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' ").

[10] 71 Fed. Reg. at 61452.

[11] 71 Fed. Reg. at 61452.

[12] Criteria for Review of Requests for CMS Research Identifiable Data, *available at* http://www.cms.hhs.gov/PrivProtectedData/02_Criteria.asp#TopOfPage (last visited Dec. 10, 2006).

[13] 71 Fed. Reg. at 61453 (internal citations omitted).

[14] 71 Fed. Reg. at 61454 (emphasis added).

[15] 71 Fed. Reg. at 61453.

[16] *See* 71 Fed. Reg. at 61446-47.

Submitter : **Ms. Sara Hogan** **Date: 12/18/2006**

Organization : **American College of Physicians**

Category : **Physician**

Issue Areas/Comments

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CMS-4119-P-95-Attach-1.DOC

ACP
AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

December 18, 2006

Leslie V. Norwalk, Esq.
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
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Baltimore, MD 21244-8017

Re: Comments on the Centers for Medicare and Medicaid Services Proposed Rule "Medicare Program; Medicare Part D Data," 71 Fed. Reg. 61445 (October 18, 2006)

Dear Ms. Norwalk:

The American College of Physicians, representing 120,000 physicians who specialize in internal medicine and medical students, appreciates the opportunity to submit comments on the Centers for Medicare and Medicaid Services (CMS) proposed rule, entitled "Medicare Program; Medicare Part D Data" published October 18, 2006 in the Federal Register.

As the largest medical specialty society and the second largest medical organization in the United States, the College is in a unique position to comment on the sharing of Medicare Part D claims data: our membership represents a wide-range of interests in internal medicine, including general internists and sub-specialists engaged in the practice of internal medicine as individual practitioners, members of group practices of all sizes, government employees, professors of medicine and medical researchers.

GENERAL COMMENTS

The College appreciates the efforts of CMS to ameliorate the fragmentation of Medicare population data by linking Part D information to other claims data, thus creating a more comprehensive data set. The College supports the reporting and evaluation of drug use within the Medicare prescription drug program, and the interaction between prescription drug coverage and services utilization under other Medicare programs. The College also recognizes the necessity of conducting claims data operations and studies to oversee the Medicare program, protect the public health, and respond to Congressional mandates. Moreover, the College believes that CMS, by engaging in this rulemaking, has resolved statutory ambiguity regarding the broad authority of section 1860D-12(b)(3)(D) of the Medicare Prescription Drug, Improvement and Modernization Act.

However, the College is concerned that CMS has not yet adequately addressed the potentially profound implications of expanding access to physician and patient information. If unique identifiers, provider prescribing patterns, and medication utilization information are shared in claims data, there could be substantial consequences for physician practices, performance

measurement programs and reimbursement formularies. The College is also concerned about potential marketing abuses if patient utilization and physician prescribing data are made available to external, non-governmental entities.

SPECIFIC COMMENTS

Purpose of CMS Collecting Information

Prescriber Information (II.B.4.d)

As a proponent of raising the quality of patient care, the College supports the concept of using Medicare Part D claims data for performance and quality improvement mechanisms to obtain better medical outcomes. However, the proposed rule must be modified to specify more clearly the conditions under which this physician data can be collected and used in performance programs, research studies, and demonstration projects. The College continues to be concerned with the burden placed on physicians to comply with multiple reporting forms, and encourages CMS to work with the private sector to minimize duplicative reporting requirements and to develop standardized reporting forms.

The College believes the goal of physician performance measurement should be to foster continuous quality improvement of clinical care that meets or exceeds evidence-based national standards of such care. Performance measures should assess and focus on elements of clinical care over which physicians have direct and instrumental control. To support performance measurement and reporting, effective data sharing requires the following:

- Transparency with respect to framework, process, and rules. Measures and methods for scoring and ranking performance should be as transparent as possible so that users and those being measured know results are valid and reliable

- Standardized and uniform rules associated with measurement and data collection.

- A process that facilitates making the data useful for physicians to improve the quality and cost of care they provide to their patients, and other appropriate purposes

- Compliance with privacy, confidentiality and other applicable rules, while ensuring that providers, plans, allied healthcare businesses, appropriate private/public entities, and consumers have necessary and appropriate access to useful information.

- Disclosures of physician-specific performance data only after participating physicians are provided an opportunity to review and comment on such data.

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Sharing Data with Entities Outside of CMS (Proposed § 423. 505.f.5)

Other government agencies (II.C.1)
The College considers it critical that provisions dealing with research use of Part D claims data recognize the delicate balance between protecting patient privacy and expanding our knowledge of health, disease, and of systems improvement mechanisms. The College supports the sharing of Part D claims data with other government research bodies, such as the Agency for Healthcare Research and Quality, Food and Drug Administration, and National Institutes of Health. Access to this data by these agencies is consistent with their missions to improve the public health, enhance the administration of health care, and promote more efficient health care financing.

External Researchers (II.C.2)
The College feels strongly that aggregated physician prescribing information should only be released to non-governmental entities with significantly clearer safeguards than currently proposed in this rule, and encourages CMS to consider additional regulatory limitations for external researchers beyond existing data use agreement protocols. Such provisions are necessary in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, and to ensure that identifiable physician prescribing data, proprietary plan data, and confidential beneficiary data are not released.

As currently proposed, Part D data claims sharing could allow for marketing of "health-related" solicitations by other entities in the healthcare system. An external researcher could be affiliated with a drug company that seeks to identify and select patients based on their health information, or physicians based on their prescribing patterns. The drug company could send patients materials encouraging patients and physicians to switch their prescriptions to the drug company's particular brand of medicine. In addition, a list of patients with certain diagnoses could be shared with a disease management company so that certain products or therapies could be promoted.

Beneficiary Access to Part D Data and Personal Health Records (II.D)

The College supports the use of personal health records (PHRs) by CMS as one mechanism of creating patient-centric repositories of clinical information. However, the proposed rule does not provide enough detail regarding the development of PHRs, or the protection of patient health information. The College has long recognized the need for appropriate safeguards to protect patient privacy, because trust and respect are the cornerstones of the patient-physician relationship and to quality health care.

The College believes that PHR data should be in a structured format that uses standardized medical terminology appropriate for a typical patient's comprehension. Beneficiaries should be able to access their health and medical data conveniently and affordably, and should receive easily understood information about all the ways that their health data may be used or shared.

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The College also recognizes that patients have a basic, fundamental right to privacy that includes the information contained in their own medical records. PHRs should be secure and adhere to all current privacy and security standards. Clinical information and guidance provided by CMS should comply with the relevant URAC standards for web-based clinical content (http://www.urac.org/consumer_standards.asp)

The College believes that beneficiaries should be able to review which entities have access to their personal health data, and should have the option of providing different levels of access to their PHRs for specific users. Beneficiaries should be able to refuse to make their health data available for sharing (i.e. opt out), and to designate someone else, such as a loved one, to have access to and exercise control over how their PHRs are shared. Additionally, the College feels strongly that PHR data shared with entities other than the individual patient should be released only in an aggregate format, without any physician identifiers.

Applicability

The proposed rule states that it does not affect the applicability of HIPAA to the Department of Health and Human Services or any other appropriate parties. Claims data use agreements will still be required in accord with HIPAA requirements to obtain patient and prescriber information. Nevertheless, the College is concerned with the over-reliance of CMS on data use agreements to protect the use and disclosure of linked and identifiable patient and prescriber Medicare Part D data. Currently under HIPAA, data use agreements are for limited data sets, and do not address the expanse of Medicare Part D claims data. The College strongly suggests that the proposed rule be modified to include clear guidance regarding HIPAA and the sharing of claims data, particularly the protection of prescriber information.

The College urges CMS to reconsider the Medicare Part D Data Rule in light of our concerns and suggestions, and to publish an interim final rule that more fully addresses the issues we have raised. Again, the College appreciates the opportunity to offer comments on this important rule, and looks forward to working with you in the future. If you have any questions regarding our comments, please do not hesitate to contact Sara Hogan, Health Policy Analyst at (202) 261-4587, or Brett Baker, Director of Regulatory and Insurer Affairs at (202) 261- 4533.

Jeffrey P. Harris

Jeffrey P. Harris, MD, FACP
Chair, Health and Public Policy Committee

Submitter : Dr. Catherine Bonuccelli **Date:** 12/18/2006

Organization : AstraZeneca Pharmaceuticals

Category : Drug Association

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-96-Attach-1.DOC

December 18, 2006

By Electronic Delivery

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

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

Dear Ms. Norwalk:

AstraZeneca Pharmaceuticals ("AstraZeneca") is pleased to submit the following comments on the Centers for Medicare & Medicaid Services (CMS) proposed rule entitled, "Medicare Program; Medicare Part D Data," published on October 18, 2006.

AstraZeneca is a leading global healthcare company dedicated to the research and development of new medicines in therapeutic areas including cardiovascular, gastrointestinal, oncology, respiratory, and neuroscience. AstraZeneca is committed to the discovery of drugs that will allow Medicare beneficiaries to lead longer, healthier and more productive lives. We conduct and support scientifically robust research that improves the delivery of effective, high-quality care to patients.

AstraZeneca supports CMS' overall objective to collect and use Medicare Part D claims data, in conjunction with other Medicare data sources, to conduct important public health research and evaluations of the Medicare program. Appropriate use of these data may ultimately enhance evidence-based decision making by physicians and patients, and strengthen the Medicare program for beneficiaries. However, it is critical that all who use these data have appropriate skills and training, understand the limitations of claims data research and communicate the results of such research carefully, noting essential caveats.

Accordingly, AstraZeneca makes the following key recommendations for incorporation into the final rule:

- Recommendation 1: CMS should provide broad access to the data to all sectors of the healthcare research community, including pharmaceutical companies.

- Recommendation 2: CMS should institute processes to ensure transparency and early engagement with affected stakeholders, including public disclosure of research topics and the types of data being accessed; consultation with pharmaceutical companies when their products are implicated in research; and, for new policy making based on research with these data, a public notice and comment period.
- Recommendation 3: CMS should continue to allow access to Medicare data by qualified researchers under current data use agreement protocols.
- Recommendation 4: CMS should clarify whether it is possible to access Chronic Conditions data Warehouse (CCW) files through a de-identified protocol (such as the Limited Data Set protocol), and if not, should explore ways to make a de-identified version of the CCW available.

The recommendations are discussed in detail in the following pages. For your convenience, our comments reference the particular portions of the proposed rule to which they apply.

AstraZeneca thanks you for the opportunity to comment on this important proposed regulation, and we look forward to continued collaboration.

Sincerely,

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COMMENTS BY SECTION

Section II A: Information to be Collected

AstraZeneca supports CMS collecting, or "accessing," the same claims information that is being collected from Part D sponsors for other purposes—that is, the 37 Prescription Drug Event (PDE) data elements. Accessing these data will allow Medicare claims datasets to include a broad range of relevant data elements that may be used for conducting research.

In the proposed rule at §423.505(f)(3), CMS characterizes the data elements to be collected as "drug claims and related information." We ask that CMS clarify that "drug claims and related information" refer specifically and only to the 37 PDE elements. If CMS determines at a future time that accessing additional data elements beyond these 37 would be necessary or useful, we strongly urge the Agency to make known its intent and take comment via a public process so that all stakeholders with an interest in data security and use can provide input.

Section II B: Purpose of CMS Collecting Information

Integrated Medicare Data Will Be A Rich Public Health Resource

AstraZeneca supports CMS' intent to collect and use Medicare Part D claims data, in conjunction with other Medicare data sources, to conduct important public health research and evaluations of the Medicare program. Appropriate use of these data may ultimately enhance evidence-based decision making by physicians and patients, and strengthen the Medicare program for beneficiaries.

Integrated Medicare parts A, B and D data will be a unique and rich resource of health care data in the U.S. While claims databases that include outpatient prescription drug utilization have existed previously, the new integrated Medicare database will be distinctive because of its size, scope and demographics. Because of the public health importance of this dataset, it is crucial that qualified experts use it for legitimate research purposes.

In the preamble to the proposed rule, CMS discusses many possible uses for the data. AstraZeneca is particularly supportive of CMS' stated interest in research on:

- How Part D interacts with Parts A and B: There is an important opportunity to use Medicare claims data to better understand the effect of a prescription drug benefit on overall Medicare program costs and associated outcomes. That is, these data enable the study of the effectiveness and efficiency of one category of technology or service *in relation to use of all other* technologies and services. We believe that making Part D data available, linked to parts A and B, will guard against siloed analysis and policy making that could have unintended consequences.

- Experience of dual eligible (Medicaid) beneficiaries in Part D: AstraZeneca agrees that it will be important to assess the effect of transitioning the dual eligible population from Medicaid pharmacy benefits into Part D, including whether these beneficiaries are receiving the same mix of prescriptions as prior to the transition, and how their out-of-

pocket costs compare. In addition, as for beneficiaries in fee-for-service Medicare, there is an important need to monitor broad public health issues such as access to care, coordination across providers and overall costs, for the vulnerable dual eligible population. Such analysis will require data from Part D linked to inpatient and outpatient data from state Medicaid agencies. We encourage CMS to facilitate this type of research.

Inherent Limitations of Claims Data Must Be Considered

While Medicare claims data present valuable research opportunities, it is crucial that CMS and all others who might use these data recognize the limitations of administrative claims data. The International Society for Pharmacoeconomic and Outcomes Research (ISPOR) Task Force on Retrospective Databases has developed a checklist to guide researchers as they consider a database for research, design their methodology and evaluate research results.[1] Similarly, the International Society of Pharmacoepidemiology has drawn up Guidelines for Good Pharmacoepidemiological Practices.[2] The work of both of these organizations underscores the variety of limitations of claims data analysis and the need for methodological rigor and highly skilled researchers. Each provides a useful framework for understanding the limits of research using claims data.

AstraZeneca would like to draw your attention to limitations of particular concern, including some Medicare-specific issues:

- ***Variable quality of coding.*** Claims data are amassed for the purpose of payment. As such, important information about patient care and outcomes may be inaccurate and unreliable. For example, diagnostic information is critical to sound research; it is a fundamental starting point for assessing and understanding other data elements. Yet, in many administrative databases, only two or three diagnoses can be captured for a claim. According to ISPOR, "the reliability of coding varies by disease state, procedure and hospital type."

- ***Important clinical and humanistic information not included.*** As with many current administrative databases, Medicare data do not include important clinical or humanistic outcomes. For example, surrogate clinical endpoints, such as LDL levels, HbA1c levels, blood pressure, or peak flow readings are not available today. Likewise, humanistic outcomes, such as ability to perform activities of daily living, frequency and severity of symptoms, sleep quality, work attendance and other factors evaluated through the use of valid and reliable survey instruments are not available.

[1] ISPOR's checklist can be found at:
http://www.ispor.org/workpaper/healthscience/ret_dbTFR0203.asp

[2] ISPE's Guidelines can be found at: http://www.pharmacoepi.org/resources/guidelines_08027.cfm

- ***Other missing information.*** In addition to missing clinical and humanistic outcomes, administrative claims data can lack information important to research because aspects of a beneficiary's care that are not eligible for payment are not captured.

  Lack of historical data is an example. For all Medicare Part D enrollees, historical claims will begin in 2006, at best. Some research questions can be answered with one year or less of pharmaceutical claims data. However, other important research topics (e.g. cost-effectiveness, long-term morbidity and mortality) will not be appropriate for study until the database includes more than one year, and in many cases, several years, of pharmaceutical claims data. Similarly, some Medicare beneficiaries may have significant pre-Medicare medical history that may not be fully appreciated from Medicare claims and diagnoses.

  Also, information gaps arise from services that are provided that are not reimbursable or are not submitted for reimbursement for some reason. For example, data will not be available on patients' use of pharmaceutical samples, over-the-counter medications, or medicines received from non-network providers that are not reported back to a beneficiary's Part D plan. The presence of a coverage gap for many beneficiaries could increase the frequency of this problem, which should be taken into account in research with Medicare Part D data.

  Finally, it is our understanding that for enrollees in Medicare Advantage plans, only Part D claims data will be available through standard CMS data access protocols, not data from the medical side of the benefit. Thus, for approximately one-fourth of Part D beneficiaries, it will not be possible to analyze the impact of pharmaceutical use on other healthcare items and services – that is, on overall patient outcomes.

- ***Inferring causality is difficult.*** Administrative claims data research can reveal correlation between variables or events, but in most cases is not sufficient to establish causation. Therefore, claims data research findings should be verified through additional research methods, especially when the intent is to use the findings to make policy.

- ***Confounding variables.*** It is difficult to separate out the effects of one variable from another in administrative claims data. Compliance to a prescribed drug regimen is a critical confounding variable to consider in observational studies about pharmaceuticals. Compliance can be imputed from administrative claims databases using methods such as average number of refills, medication possession ratio, etc. However, unlike in clinical trial research, patients don't get assigned to a treatment group and they may stop taking therapy for any number of reasons. Such information will not be available in the Part D data, but will impact overall outcomes.

  The Part D benefit design is another potential confounding variable. The potential effects of the coverage gap on beneficiary behavior and outcomes are not yet understood. Whenever feasible, research results should be viewed as suggestive of overall trends, then verified by more well controlled clinical evaluations to minimize bias and confounding variables.

As evidenced by this list, administrative claims data – while an important research tool – do not provide a complete picture of a beneficiary's care. Due to these limitations, it is critical that those who do research with these data have training in a relevant discipline, and, ideally, a proven record of conducting and publishing sound research with administrative data.

AstraZeneca believes all research conducted with Medicare claims data should follow well-established conventions of scientific investigation, including identification of clear, concise research questions and hypotheses, identification of the patient population including exclusions or adaptations, and a description of the intended research methods and analysis plan. The limitations of the dataset and analyses should be clarified and described. Without such conventions, the research cannot be taken as a valid basis for making scientific conclusions or healthcare policy.

Specific Recommendations

AstraZeneca is concerned that the Medicare claims dataset could be used without full understanding of its limitations, or could be made public or used for policy making without the full disclosure of caveats and limitations. Such research could lead to misinformation about the Medicare program and the services and technologies it covers. It could also lead to policy making that adversely affects beneficiary care.

For these reasons, we believe it is critical that CMS create a robust and transparent process for gaining access to and conducting research with these data. The following recommendations are meant to ensure that the full potential of research with these data is realized, and the public is not harmed by misleading research or ill-founded policy decisions.

Recommendation 1: Broad Access

CMS should provide broad access to the data to all sectors of the healthcare research community, including pharmaceutical companies. We believe an effective way of ensuring the data are used appropriately is to allow a wide range of qualified researchers access to the data. Doing so will help ensure that research can be appropriately vetted through traditional peer review processes, as well as provide opportunities for researchers to replicate the results of previously published studies.

We appreciate that CMS has devoted a section of the proposed rule to data use by those other than CMS, including "external researchers" [Section II C, 1 and 2]. More specific recommendations on this issue are included in reference to that section below.

Recommendation 2: Transparent and Participatory Process

Two other important tools to ensure rigorous use of these data by researchers and policymakers are transparency in how the data are being used and early engagement of affected stakeholders in policy making based on research results. We suggest that CMS institute a process that includes the following elements:

- Public disclosure of research topics. For all data access requests that are granted, CMS should make public the proposed research topics and the types of data being accessed. This should apply for all parties that request Medicare data, including CMS, other government agencies and external researchers.

- Consultation with pharmaceutical companies. The pharmaceutical industry employs thousands of distinguished research professionals with expertise in a wide range of research disciplines and therapeutic areas. AstraZeneca believes that industry can provide valuable, and often unique, input to research studies to enhance their overall quality and public health benefit. Therefore, we urge government agencies and their contractors to include as a standard process early outreach to and opportunities for input by pharmaceutical companies whose products are implicated in their research.

- For new policy, public notice and comment opportunity. CMS, as well as other agencies that use these data, should adopt a public notice and comment process to vet new policy proposals that are based on research with these data. Given the limitations of claims data discussed above, we believe that giving the public an opportunity to comment will ensure a broad array of perspectives and knowledge are brought to bear on important decisions, such as new Part D regulations and legislative proposals discussed by CMS in Section II B, that could affect beneficiary access to care.

Section II C 1.: Sharing Data with Entities Outside of CMS, Other Government Agencies

AstraZeneca believes that Medicare data should be available to a wide range of researchers, consistent with current CMS policy for the use of Medicare parts A and B data, including other government agencies. We concur with the proposed uses of the data by other agencies as outlined in the Preamble. In particular, we would support research on the impact of drug use on overall outcomes and use of technologies and services (i.e., analyses of integrated claims data versus Part D data alone). Below are some specific comments on the use of the data by HHS agencies other than CMS.

- Use of the data by the Agency for Healthcare Research and Quality (AHRQ): Observational research with integrated claims data can aid in making conclusions about comparative effectiveness when used in combination with other research, including prospective clinical trials. We urge AHRQ to follow this approach.

  The processes that AHRQ has put in place for the Effective Healthcare Program, including transparency of research questions, peer review of draft reports, opportunity for public comment, and direct engagement with parties whose products are implicated, are appropriate. We look forward to AHRQ applying these same processes when conducting studies using Part D data or integrated A, B and D data.

- Use of the data by the FDA: We agree that integrated Medicare parts A, B and D data offer the possibility of improved post-marketing drug safety surveillance. Some of the unique benefits would include the ability to monitor large cohorts of patients, to study the very elderly and to follow patients over very long periods of time.

However, we caution that safety confirmation and causality should be verified using more rigorously designed clinical trials and analyses, including medical chart reviews and continuous medical surveillance. The process is exacting and requires that specific skills and disciplines be brought together.

Based on our experience, the limitations of administrative data are just as relevant to post-marketing surveillance as to other applications. When we have used integrated claims data for safety analyses, we have worked with vendors who are intimately familiar with the insurer's coverage policies, have access to lab values, and can access patient medical records to confirm patient outcomes suggested by the claims data.

It is important that, as the FDA uses these data in the post-marketing surveillance area, the pharmaceutical industry be permitted to do the same. Together, the FDA and the pharmaceutical industry play a critical role in this public health arena. Our joint objective to provide up-to-date safety information that is accurate, timely and specific can only be accomplished by analyzing and interpreting databases that are clearly defined and shared so that the best conclusions are drawn and communicated during a product's post-approval life cycle.

Finally, we note that administrative claims data analysis for post-marketing safety surveillance is likely to present distinct challenges. We believe that the FDA should play the central role in addressing such challenges – a role that is clearly within the Agency's mission to evaluate the efficacy and safety of pharmaceutical products.

Section II C 2.: Sharing Data with Entities Outside of CMS, External Researchers

AstraZeneca notes that the question of who should be able to access integrated Medicare data, and for what uses, is of crucial importance. We appreciate the opportunity to provide comments on this issue.

Specific Recommendations

Recommendation 3: *Access Through Current Protocols*

As suggested in Recommendation 1, we support CMS' proposal to continue allowing access to Medicare data by all qualified external researchers under current data use agreement protocols. Broad access to the data by a variety of parties, including commercial entities (e.g., pharmaceutical companies, health plans, etc.) is both consistent with current policy and the right approach to maximize the use of these data for public health purposes.

Our work demonstrates that private commercial entities do conduct research with Medicare data that advances the public health:

- Using Research Identifiable Files (RIF) and working through the Chronic Disease Research Group of Minneapolis, MN, AstraZeneca sponsored a study on the incidence of Atrial Fibrillation and the uptake of warfarin use in a Medicare population

over a 10-year period[3]. This is an important example of a private, commercial entity utilizing the Medicare data to conduct research to advance public health.

- AstraZeneca also has been using a Limited Data Set (LDS) for studies of the incidence and prevalence of diseases, mortality and comorbidity patterns and treatment patterns in various treatment settings for a range of diseases including cardiovascular, oncology, respiratory, central nervous system, infectious, metabolic, auto-immune, and musculoskeletal.

When considering Medicare data, AstraZeneca's greatest interest is in using de-identified data (the LDS) for health research. In general, we have found that the LDS is a robust and useful resource. However, we have encountered some limitations with LDS data. For example, time of service is provided by quarter, rather than month. Patients can experience several medical events in a three-month time period – particularly elderly patients and those with multiple co-morbidities - and the sequence of those events can be critical to performing sound research. Therefore, summarizing service date to quarter compromises our ability to conduct research and draw meaningful conclusions on issues such as drug safety. We would like to make sure that the LDS is as useful as possible, and we would be interested in discussing this and any other limitations of the LDS with CMS.

Recommendation 4: *Clarification on Access to the CCW*

It is our understanding that the Chronic Conditions data Warehouse is considered an identifiable data file. We ask that CMS clarify this point. If this is correct, we encourage CMS to explore ways to make a de-identified version of the CCW available to external researchers

Conclusion

AstraZeneca supports CMS' overall objective to use Medicare Part D claims data, in conjunction with other Medicare data sources, for research, analysis and other public health functions. Appropriate use of these data may ultimately lead to enhanced evidence-based decision making by physicians and patients, and a stronger Medicare program for beneficiaries.

It is critical that all who use these data have appropriate skills and training, understand the limitations of claims data research and communicate the results of such research carefully, noting essential caveats. To this end, AstraZeneca makes the following recommendations for incorporation into the final rule:

- Recommendation 1: CMS should provide broad access to the data to all sectors of the healthcare research community, including pharmaceutical companies.
- Recommendation 2: CMS should institute processes to ensure transparency and early engagement with affected stakeholders, including public disclosure of research topics and the types of data being accessed; consultation with pharmaceutical companies when their

[3] Lakshminarayan K, Solid CA, Collins AJ, et al. Atrial Fibrillation and Stroke in the General Medicare Population: A 10-Year Perspective (1992 to 2002) *Stroke* August, 2006;1969–1974.

products are implicated in research; and, for new policy making based on research with these data, a public notice and comment period.

- Recommendation 3: CMS should continue to allow access to Medicare data by qualified researchers under current data use agreement protocols.
- Recommendation 4: CMS should clarify whether it is possible to access Chronic Conditions data Warehouse (CCW) files through a de-identified protocol (such as the Limited Data Set protocol), and if not, should explore ways to make a de-identified version of the CCW available.

Submitter : Mr. Steve Lieberman **Date:** 12/18/2006

Organization : The Moran Company

Category : Other

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-97-Attach-1.PDF

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VIA ELECTRONIC MAIL

December 18, 2006

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

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

Dear Administrator Norwalk:

The Moran Company LLC (TMC) is pleased to submit the following comments on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding collection of and access to claims data under Part D of the Medicare program (the "Proposed Rule").[1] TMC is a health care research and consulting firm that primarily assists private sector providers, trade associations and manufacturers by analyzing Medicare payment, coverage and other policies. As an essential part of these activities, TMC builds microsimulation models and conducts research aimed at providing objective information to decision makers on how changes in policies or alternatives to proposed policies may affect access to Medicare services, as well as the financing or quality of those services.

TMC supports the Administration's emphasis on promoting transparency in health care, and specifically to promote transparency in Medicare. We believe that providing micro data on Medicare claims is essential to informed analysis and meaningful transparency. We recommend that Part D Prescription Data Elements (PDE) data be made available, much as Part A and Part B claims data are made available for analytic purposes. TMC urges CMS to allow for a process for outside analysts to replicate the results of the rule-making or research of CMS and other agencies using Part D claims data.

The highlights of TMC's specific comments are as follows:

- The capacity to provide key research to decision makers in health care could be greatly enhanced by access to Part D claims information, provided that access is available in an organized way.

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

- Consistent with maintaining strong privacy protections, the definition of "commercial purposes" must be narrowly construed so that the use of the data is not compromised and access to vital information that promotes sound analysis and research is not hindered.
- The data should be made available to the public in a timely manner and in forms that facilitate sound research by the public.

The balance of this letter provides more information in each of these areas.

I. The Importance of Public Access to the Data

TMC agrees with CMS that the data the agency proposes to collect could be extremely valuable to CMS and other federal agencies in their efforts to protect the public health and provide health care services to Medicare beneficiaries. As noted previously, access to micro data is essential to promote transparency. In order for Medicare providers and other concerned parties to offer analytically informed comments on CMS regulations and other proposed policies, responsible analytical firms and other researchers (such as TMC) must be able to independently analyze Medicare data.

TMC believes that Part D PDE data, especially when linked to currently available claims data from Medicare Parts A and B, would greatly enhance efforts to study issues related to the use of Medicare services by beneficiaries. We believe that the potential benefits from this research—to Medicare beneficiaries, Medicare providers, other stakeholders, and the nation as a whole—would outweigh any concerns about potential commercial benefits. We believe that concerns about potential commercial applications can best be addressed through existing Privacy protections and requirements.

CMS should ensure that the data it proposes to collect are available to the public in much the same manner that claims data from Parts A and B are available currently. It is important that the Part D PDE data can be linked at the beneficiary level (while maintaining confidentiality and avoiding potential re-identification) to key CMS Part A and Part B data files. An example of key files includes the 5% sample Standard Analytical Files (SAF) that can be linked using encrypted identifiers on Part A and B claims. These data should be drawn from the same 5% sample used for existing SAFs, even though some sampled beneficiaries will not be enrolled in standalone Prescription Drug Plans (PDP). In addition, TMC urges CMS to consider developing and releasing a summary file (of manageable size) that parallels the current Physician Supplier Procedure Summary Master file.

In constructing these files, we would urge CMS to include as many data elements from the Part D claims information as possible, without jeopardizing beneficiary privacy, to ensure research can control for as many confounding elements as possible. (This is also why linkage to Part A and Part B data is essential.) Detailed information about PDP formulary and tiering structures, as well as diagnosis codes, will be particularly useful in this regard. To protect these data from being used to identify and target particular physicians, which we believe would constitute an inappropriate commercial purpose, we would suggest encrypting the physician UPIN identifier in the same manner now used in the carrier and DME SAFs—though this should be done in a

consistent way for each UPIN so that physicians could be tracked in the data (but not individually identified).

CMS may also wish to consider constructing a mechanism to allow outside researchers to access Part D claims information for pharmacosurveillance purposes. Such a mechanism would require an investment of time and resources materially greater than a SAF release, but could generate significant improvements in the quality of research available to decision makers by expanding the pool of researchers and studies examining PDE data for pharmacosurveillance.

Unfortunately, the utility of pharmacosurveillance would be hindered under the current system of CMS data releases, which includes lags in data release of up to two years. Moreover, a dataset that was specifically designed to be used for pharmacosurveillance could be a subset of those data available on the SAFs and a more refined file layout specifically for these efforts. TMC believes that a refined layout and the ability to access data in a timely manner would add significantly to the ability of outside researchers to conduct pharmacosurveillance and would greatly increase the likelihood that these activities would improve the safety and efficacy of drug use among Medicare beneficiaries.

II. Defining "Commercial Purposes" and Protecting Beneficiary Privacy

In the proposed rule, CMS requested comments on whether it should consider additional restrictions to guard against "the potential misuse of data for non-research purposes, commercial purposes or to ensure that proprietary data or confidential beneficiary data is not released."[2] TMC believes that the current protections for claims data released under Parts A and B, through the use of the Privacy Board for claims data that are considered fully identifiable, and research protocols with data use agreements for Limited Data Set (LDS) releases provide adequate protection of beneficiary privacy. We assume that LDS releases of Part D claims information will remove or encrypt data elements in much the same way that the current SAF LDS files are constructed, effectively preventing the re-identification of individual beneficiaries. However, we would again urge the agency to release as many data elements as possible while continuing to protect beneficiary privacy.

Given our desire to assure that the data in question—and the benefits these data offer—are available to the public for a broad range of beneficial analyses, TMC believes that CMS should construe "commercial purposes" as narrowly as possible. We believe that any analyses concerning the use of claims information in the legislative, regulatory, administrative or judicial processes cannot be considered a commercial purpose, even though the entities that may wish to conduct these analyses might be commercial entities.

We do agree with CMS, however, that some potential uses of the data should be impermissible; we believe that these uses can be prevented with a targeted definition of "commercial purpose." We urge CMS to limit restrictions based on commercial uses to those situations where entities are seeking to use Part D claims information to identify beneficiaries or pharmacies in order to

[2] *Id* at 61453.

solicit commercial transactions. These sorts of uses of the data can be restricted through the use of encrypted pharmacy and plan identifiers—in much the same way that Physician identifiers are encrypted in current SAF files.[3] We are concerned that a broader definition of "commercial purpose" could create undue restrictions on usage of this information.

TMC believes that a narrowly defining those uses of Part D claims information that are prohibited will serve to provide the greatest benefit to Medicare beneficiaries, allowing researchers the flexibility to explore the data while seeking to improve the safe and effective usage of prescription drugs and other treatments for Medicare beneficiaries and the healthcare system as a whole.

In summary, TMC supports CMS in its mission to ensure that beneficiary privacy is carefully protected. We believe that the agency has done an excellent job in this effort and agree that continued efforts are needed to protect the security of beneficiary claims data, while also allowing access to Part D claims information that will provide significant benefits to Medicare beneficiaries. We agree that commercial uses of the data should be restricted, but that this restriction should allow adequate flexibility for a wide range of research that has the potential to improve the safety and effectiveness of prescription therapies.

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TMC appreciates the opportunity to offer these comments. We look forward to continuing to work with CMS to address these critical issues in the future. Please feel free to contact Steven Lieberman at 703-841-8404 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Respectfully submitted,

Steven Lieberman

[3] If the agency does decide to encrypt pharmacy and plan identifiers, we are hopeful that some descriptive information will be released. For instance, information about the nature of the pharmacy (mail order, retail, specialty, and/or geographic regions) would be necessary to control for possible confounding factors in outcomes studies.

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

Organization : Committee on Energy and Commerce

Category : Congressional

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-98-Attach-1.DOC

December 18, 2006

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

Re: File Code CMS-4119-P

Dear Ms. Norwalk:

As the Chairmen-elect of the Committees on Energy and Commerce, Government Reform and Ways and Means with jurisdiction over Part D, we respectfully submit the following comments on the proposed rules (CMS-4119- P) entitled "Medicare Program; Medicare Part D Data," issued October 18, 2006.

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

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

Purpose of CMS Collecting Information

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

Sharing Data with Entities Outside of CMS

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

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

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

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

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

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

Limitations

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

Sincerely,

John D. Dingell
Chairman-elect
Committee on Energy & Commerce

Charles B. Rangel
Chairman-elect
Committee on Ways & Means

Henry A. Waxman

Chairman-elect
Committee on Government Reform

Submitter : Dr. Melinda Beeuwkes Buntin **Date:** 12/18/2006

Organization : RAND

Category : Academic

Issue Areas/Comments

GENERAL

GENERAL

Please see attachment.

CMS-4119-P-99-Attach-1.DOC

Dear Ms. Norwalk:

I am writing to comment on CMS's Proposed Rule regarding Medicare Part D Data, file code CMS-4119-P, in my role as the RAND Corporation's Director of Public Sector Initiatives and MRAD Contract Coordinator.

I commend CMS for seeking input on the uses of Part D data and believe that these data will provide a vital resource for research on how to improve Medicare operations, the health of Medicare beneficiaries, and the health of all Americans. I would like to emphasize, above all, that use of these data should be no more restricted that is currently the case for other types of Medicare data – and that ideally the data would be made even more readily available to persons engaging in serious research projects for the benefit of public health. I would also like to make the following comments about each of the major sections of the provisions of the proposed rule.

Information to be collected

In terms of the information to be collected, we feel the data elements listed in the proposed rule are all key items and all should be collected as part of this effort. In addition, it would be helpful to include information on the file about the beneficiaries' enrollment history in the given Part D plan. While this information will likely become part of another file (e.g. the denominator file or a Part D plan file) it would be easier for researchers to use the file if it contained key enrollment data elements. It would also be useful for CMS to push towards the collection of standard provider identifiers such as the National Provider Identifier (NPI).

Purpose of CMS Collecting Information

Second, in terms of the purpose of CMS collecting the information, we would argue that the data should be available for any legitimate project that could improve health and welfare. This includes the range of valuable projects listed in the proposed rule but could also include projects seeking to draw inferences beyond the Medicare Part D program or comparing the Medicare Part D program to other alternatives. We would urge CMS to automatically deem projects judged worthy of funding by other federal entities (e.g. the National Institute on Aging, the Medicare Payment Advisory Commission) within the legitimate purposes of collecting these data. We would also urge CMS to set up a process by which other research projects that would benefit the public could be approved, such as those conducted by graduate students or sponsored by independent foundations. The Part D data are potentially so rich and valuable for research that it would be a mistake in our opinion to prejudge the range of topics to which it might fruitfully be applied.

Sharing Data with Entities Outside of CMS

Finally, we agree with CMS' statement that the Parts A and B claims data have been extremely useful to government and external researchers and that their efforts have contributed to the Medicare program and the clinical care of beneficiaries. We believe

that the addition of Part D data will make the entire set of claims even more valuable. Accordingly, we would like to urge CMS not to make access to these data any more difficult than is current access to other types of Medicare claims data. Indeed, we would like to request that CMS make its processes and charges for obtaining the data and executing Data Use Agreements less onerous. This might be done by creating standard files that are deidentified and available at low cost.

In addition, since we are aware of no instance in which data have been compromised under the current set of rules, we believe that more valuable research could be conducted, with minimal additional risk, if data use were facilitated.

We appreciate the opportunity to comment and would be happy to discuss these comments with any interested CMS officials.

Sincerely,

Melinda Beeuwkes Buntin Ph.D.