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

Organization : **American Pharmacists Association**

Category : **Pharmacist**

Issue Areas/Comments

Applicability

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American Pharmacists Association

Improving medication use. Advancing patient care.

APhA

December 18, 2006

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

Re: CMS-4119-P

Dear Sir/Madam:

APhA appreciates the opportunity to comment on the October 18, 2006 *Federal Register* notice proposing to allow the Secretary of the Department of Health and Human Services to share Part D claims data for research, analysis, reporting, and public health functions. The American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 57,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA is the nation's first and largest association of pharmacists in the United Sates.

The creation of a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs within the Medicare Part D prescription drug benefit is of great interest to APhA and its members. Allowing researchers to link Medicare Part A and B data with Medicare Part D data will be an invaluable resource. This type of comparison will facilitate the evaluation of the overall Medicare program and the impact Part D has on Medicare Parts A, B and C.

Of particular value would be linking the data from Medicare Part D medication therapy management (MTM) services with Medicare Parts A, B and C data. As the Agency is aware, Part D plans are required to provide a subset of chronically ill Medicare beneficiaries with an MTM program. MTM programs may encompass a broad range of professional services provided by pharmacists or other qualified health care providers. Like the Agency, APhA believes a robust MTM program can significantly improve patient health outcomes. To evaluate the effectiveness of MTM programs, Part A, B, and C data must be captured and linked to Part D MTM data.

APhA's members are committed to advancing patient care through improved use of prescription and over-the-counter medications. Pharmacists can have a tremendous positive impact on appropriate medication use. We envision that APhA's scientist members in particular would take advantage of this opportunity to conduct studies on the successes of the Part D benefit including MTM programs.

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www.aphanet.org • www.pharmacist.com

APhA offers the following comments on the Proposed Rule as published in the October 18, 2006 *Federal Register* Notice.

II (A) Information to be Collected

APhA strongly recommends that the Agency expand the proposed information to be collected to include medication therapy management data. We appreciate the challenge this presents because MTM data is not currently part of Part D claims data. However, groups such as the PQA (a pharmacy quality alliance) are working on standard quality metrics that will eventually be reported. We strongly encourage the Agency to incorporate these or other appropriate data elements as they become available. Capturing MTM data — what service is provided and by whom — is essential to measuring the impact of MTM.

II (B) Purpose of CMS Collecting Information

Evaluations of the Medicare Program (II.B.2)
As stated above, APhA strongly supports the use of Part D data to evaluate the overall Medicare program and how the prescription drug benefit impacts Medicare Parts A, B and C. When Parts A, B and C data is linked to Medicare Part D data we will gain greater insight into how Part D impacts other programs, including whether it decreases spending in these programs by helping patients to avoid more costly care such as inpatient hospitalizations and outpatient office visits.

Demonstration Projects and Research Studies (II.B.4)
APhA strongly supports the use of Part D claims data by CMS to conduct demonstration projects that could identify ways to improve the economy, efficiency, or effectiveness of the Medicare program. The availability of publicly funded comparative effectiveness studies of prescription medications and other treatments will provide important objective information on the relative effectiveness of different prescription drugs and other therapies used to treat the same condition. The use of Part D data will play an important role in supporting these research activities. Part D data may also assist with surveillance of the prescription drug market, particularly with regards to safety and efficacy.

We also support the use of drugs dispensed data to refine identification of beneficiaries with chronic conditions. The CCW data can be used to perform studies that examine medication adherence and persistence patterns. Adherence and persistence are specific elements identified in the Medicare Modernization Act for MTM programs. An analysis of medication usage for these beneficiaries linked to the services delivered is an important step towards identifying the best care for these patients.

At the same time, APhA does not support the use of such research for commercial purposes, and encourages CMS to emphasize that Part D data will not be used for such purposes.

Sharing Data with Entities Outside of CMS

Regardless of with whom the data is being shared, it is imperative that the Agency ensure that patient information is protected and that identifiable information is not shared. Therefore, we support the Agency's preamble statement that the Agency "appropriately guard against the potential of misuse of data in ways that would undermine protections put in place to ensure confidentiality of beneficiary information". To that end, we recommend that the Agency address the need to collect information that

is non-identifiable, to include appropriate security protections that protect patient privacy, and to ensure adherence to Health Insurance Portability and Accountability Act (HIPAA) requirements.

Other Government Agencies (II.C.1)
APhA supports the sharing of Part D claims data with entities outside of the Agency. APhA agrees with the Agency that Department of Health and Human Services' public health agencies such as NIH, FDA, and AHRQ have researchers who would benefit from using Medicare Part D prescription drug related data for studies that could improve public health. In particular, APhA supports data sharing with the Food and Drug Administration (FDA), which may help FDA identify potential drug-related problems.

Furthermore, while CMS specifically discusses sharing data with "other government agencies" and researchers, the government agencies listed in the preamble are limited to federal public agencies. We recommend that the Agency consider expanding this list to include State Medicaid agencies and the State Children's Health Insurance Program (SCHIP). As the Agency asserts in the *Evaluations of the Medicare Program, II.B (2)* section of the preamble, in order for CMS to evaluate the overall Medicare program, it is necessary to evaluate how the prescription drug benefit interacts with benefits provided under Parts A, B, and C, as well as Medicaid and the SCHIP program. State Medicaid agencies and SCHIP programs would benefit from being able to access Part D claims data directly. Therefore, we recommend that the Agency state that it intends to share Part D data with State Medicaid agencies and SCHIP programs.

Finally, while APhA supports other agencies having access to Part D data, APhA strongly recommends that CMS set specific limits to ensure the data is not used for commercial purposes.

External Researchers (II.C.2)
APhA supports the implementation of section 723 of the MMA by populating a chronic care condition warehouse (CCW) with Part D claims data that would be accessible by private researchers to facilitate conducting studies related to improving quality and reducing costs of care for chronically ill Medicare beneficiaries. As we stated earlier, APhA recommends that the claims information used to populate the CCW should also include MTM data. Linking the Parts A, B and C data to Part D data within the CCW will provide a more complete picture of a chronically ill beneficiary's care and would help determine whether the treatment of chronically ill beneficiaries is as effective and efficient as possible.

APhA believes that Part D data could be used for the following research purposes:

1. Tracking medication use and the types of medications prescribed to the Medicare population.
2. Determining whether formalized clinical criteria (for example the "Beers Criteria") are being followed.
3. Determining whether potentially inappropriate medications are being avoided.
4. Tracking how individual patients are obtaining their medications, for example, through mail-service pharmacies, community pharmacies, etc.
5. Determining which medications are prescribed and which medications are being used by the Medicare population.
6. Determining drug-spend by the Medicare population.
7. Determining any regional differences in prescribing and dispensing.
8. Determining overall patient satisfaction with plans by looking at the numbers of Part D beneficiaries who changed plans.
9. Determining overall patient satisfaction with pharmacy services.

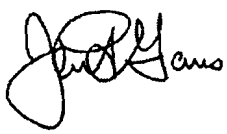
10. Determining how MTM services impacted appropriate use of medications, overall patient health, and health care costs.

Beneficiary Access to Part D Data

While APhA generally supports the use of Part D claims data for projects involving the development of a personalized medication record that would be accessible by Medicare beneficiaries, further clarification by CMS on beneficiary access to Part D data is necessary. Additionally, APhA encourages the Agency in its development of any electronic medical record to develop it in a way that captures all medications used by Part D beneficiaries, including over-the-counter (OTC) medications, herbal and other dietary supplements, and non-Part D covered drugs.

Thank you for your consideration of the views of the nation's pharmacists. Please contact Kristina Lunner, Acting Vice President of Policy and Communications, at 202-429-7507 or KLunner@APhAnet.org with any questions.

Sincerely,



John A. Gans, PharmD
Executive Vice President

cc: Kristina E. Lunner, Acting Vice President of Policy and Communications

Submitter : Mr. Matthew Eyles **Date:** 12/18/2006

Organization : Wyeth Pharmaceuticals

Category : Drug Industry

Issue Areas/Comments

GENERAL

GENERAL

See attachment. Wyeth Pharmaceuticals appreciates the opportunity to submit comments on the Medicare Part D Data Proposed Rule.

CMS-4119-P-106-Attach-1.DOC

Wyeth Pharmaceuticals
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Collegeville, PA 19426

Matthew D. Eyles
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Wyeth

December 18, 2006

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

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

Dear Ms. Norwalk:

Wyeth Pharmaceuticals appreciates the opportunity to submit comments on the proposed rule of October 18, 2006, on the use of claims data collected under Part D of the Medicare program (Proposed Rule). Wyeth Pharmaceuticals, a division of Wyeth, is one of the world's largest research-driven pharmaceutical and health care products companies with leading products in areas of women's health, central nervous system, inflammation, hemophilia, transplantation, oncology and vaccines.

Wyeth believes that Medicare claims data can provide valuable insights about the provision of healthcare to beneficiaries and supports the spirit of the Proposed Rule. We also support efforts by CMS to facilitate the use of these data. At the same time, we do have some concerns about the lack of detail in the Proposed Rule around how the data will be implemented and which data will be used for policy decision-making.

The Proposed Rule identifies a broad range of potential research that could incorporate the integrated claims data from Parts A, B and D. It also requires updates and clarifications to CMS policy to provide for appropriate access to claims data for research while protecting patient privacy and confidentiality. Wyeth respectfully submits the following detailed comments and recommendations on the Proposed Rule.

Wyeth

Summary of Wyeth Comments

Sharing Data with Entities Outside of CMS

- Wyeth believes that all qualified external researchers, including commercial entities conducting legitimate public health research or commenting on federal policies, should be able to access the Medicare claims data.

Purpose of CMS Collecting Information

- CMS should not seek to define a national research agenda for external researchers interested in using Medicare claims data and should be explicit about the priorities of federally sponsored research.

- Wyeth believes that any research using Medicare claims data, whether it is in the private or public sector, should include and be explicit about the limitations of such data and how those limitations impact the research project.

- Integrated claims data can be used to monitor patient safety but should be used carefully and in close collaboration with the FDA.

- Proposed and implemented CMS policies (or other federal agencies) that use these claims data, such as decisions relating to Medicare coverage and payment, should be transparent and specific as to the data used and analysis performed in support of the decision.

- Wyeth believes that the pricing information contained in the Part D claims do not accurately reflect the actual cost of drugs to Medicare drug plans. We suggest that CMS note the inaccuracy of the claims information and reiterate the confidentiality of actual pricing data.

I. Sharing Data with Entities Outside of CMS

Wyeth believes that all qualified external researchers, including commercial entities conducting legitimate public health research or commenting on federal policies, should be able to access the Medicare claims data.

Like many commercial medical product and health service entities, Wyeth invests billions of dollars annually in clinical and clinically related research. When such

Wyeth

clinical research adheres to accepted scientific protocols and standards, this research is routinely accepted by the Federal government and recognized as necessary, unbiased, valid and in the public interest. While we have been able to produce evidence to support the appropriate use of our products by patients in need of medical therapies, the release of Part D claims information linked to claims data from the other parts of the Medicare program would provide a rich new resource for researchers interested in these issues.

We understand that CMS does not want federally generated health-related data to subsidize the costs associated with the commercialization of medical products. We agree but also believe appropriate circumstances exist where individuals and private sector organizations (e.g., physicians, health insurers, pharmacy benefit managers, pharmacies, and pharmaceutical, medical device and diagnostics manufacturers) should also have access to such data, providing the appropriate safeguards are in place to ensure patient privacy. By limiting the entities with access to the data, CMS may also be limiting research into key public health questions or forgoing potential innovations brought forth by the private sector into how to examine the data.

It is also important for CMS to recognize that all parties—including federal and state government researchers and organizations, academics, and other external researchers—may have biases, including the identification of research questions to which they seek answers and others they wish to avoid. We believe that broad access is an effective means of ensuring high quality research, as this would allow for validation of research results from multiple perspectives and for all stakeholders to offer fully informed comments on any initiatives that CMS or other agencies pursue based on data collected under the Proposed Rule.

In addition, subject to appropriate protections for patient privacy and confidential trade or proprietary information, the final rule should specify that all qualified external researchers will have equal access to Medicare Part D data under the same terms. Restrictions on access to data by external researchers should not be based on the type of organization or funding source (whether external researchers are performing government-supported or privately-supported analyses) but on the researchers' qualifications, the legitimacy of the research question and the soundness of the research protocol.

Wyeth

To provide greater assurance that claims data will not be used for commercial purposes, CMS could consider identifying specific uses of data (e.g., use of data to create a research tool for sale to others, use of data for competitive market analysis) that would be excluded as commercial purposes. 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.

Finally, to ensure timely and fair action on data requests, for external data requests, CMS should apply a "first in, first reviewed" policy. We understand that the agency may need to make exceptions to this policy in some cases, but it should establish the concept as a general rule.

II. Purpose of CMS Collecting Information

CMS should not limit the types of research questions investigated by defining an exclusive research agenda or list of acceptable topics for external researchers. Instead, it should identify priorities for federally-sponsored research and other research under an open and public process. CMS should also apply existing policy on data use agreements for Part D data.

CMS specifically solicits input on the "proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health." In addition, CMS requests 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]

CMS should not explicitly define a set of exclusive research topics for which it will release claims data; rather, it should approve requests for data on a broad range of legitimate research questions that can expand the evidence base and contribute to improved health care and policy decisions. We also believe existing policy on data use agreements provides a sound basis for release of data and that additional regulatory limitations should not be applied.

[1] 71 Fed. Reg. at 61453

Wyeth

Further, the Final Rule should describe an open public process—e.g., following Notice of Proposed Rulemaking (NPRM) procedures—for establishing priorities for federally sponsored research using integrated claims data. This process should ensure there is continuing, broad, and public collaboration with relevant stakeholders to identify the highest priorities for research, demonstrations, and evaluations. The collaboration should be captured in an administrative record so that the rationale for and input on research priorities can be clearly understood.

Methodological Issues

Wyeth believes that any research using Medicare claims data—whether in the private or public sector—should include and be explicit about the limitations of such data and how those limitations impact the research project.

Research based on integrated (Parts A, B, and D) claims data can help describe important issues such as the quality of healthcare, the cost of non-adherence to therapy, and the impact of benefit design on medication use. At the same time, there are significant limitations in the range of analyses that can be performed using Medicare claims data alone. For example, in regards to quality assessment, claims data could provide information on performance on some quality measures, such as use of a beta-blocker after a heart attack, but not on others like control of blood glucose levels in diabetics.

As CMS indicates in the Proposed Rule, the Part D data that the agency proposes to use for a variety of purposes were originally designed to assure accurate payment of Part D plans, reflecting "True Out of Pocket Costs" (TROOP). While these data could be used for a number of other purposes, the data elements available will not always be exactly on point for the questions that CMS and other agencies will be seeking to answer.

Often the information will provide only surrogates for the actual information being sought. For example, the diagnosis data contained in claims data may not accurately reflect the condition of the patient because diagnostic codes used in claims data often are used for procedures to rule out a diagnosis. In addition, because claims data do not include results of diagnostic testing and information in the medical record, such data cannot alone provide a complete picture of beneficiary health status. Therefore, it may not be possible to use the data to

Wyeth

evaluate the effectiveness of specific therapies.

Further, unless CMS requests detailed documentation for payment, there may be little incentive to accurately document the patient encounter. This is especially the case in settings of care with bundled reimbursement for a patient's care (e.g., DRGs). Without proper incentives, administrative claims may suffer from inaccuracies and a high prevalence of missing data.

Wyeth recommends that CMS sponsor and publish an external analysis of the methodological issues associated with using claims data for making policy decisions and allow for public comment on that analysis.

To ensure the successful use of Part D claims data, it will be important for all stakeholders to recognize the challenges and limitations of research using claims data and to take steps to ensure that results are valid and appropriately communicated. It is also important there be a common understanding of the strengths and weaknesses of these data to support subsequent public acceptance of decisions made on the basis of these data.

Wyeth believes that the integrated claims data can be used to monitor patient safety but should be used carefully and in close collaboration with the FDA.

Traditionally, the randomized controlled clinical trial is considered the gold standard methodology to study the safety and efficacy of a drug. However, trials may be limited by the relatively small numbers of patients studied and the short time period over which patients are observed. Clinical trials also usually have strict inclusion/exclusion criteria and their results may not reflect "real world" experience.

Spontaneous reporting systems are valuable for identifying relatively rare events and for providing signals about potentially serious safety problems. However, spontaneous reports are voluntary and subject to many biases and external influences on reporting rates. Often the information provided is incomplete or inaccurate, and it is impossible to know the degree of under reporting. Despite these limitations, spontaneous reports are used to detect signals and alert companies and regulators of safety issues that require further investigation.

Wyeth

More recently, pharmacoepidemiology studies have been conducted to detect and evaluate safety issues using large record linkage and automated databases, including hospital databases and insurance claims databases. These databases have both strengths and weaknesses.

Strengths include their potential for providing a very large sample size. In addition, these databases are relatively inexpensive to use—especially compared to the cost of clinical trials—since they are part of existing administrative systems. The data can be complete, i.e., for claims databases, and information is available on all medical care provided.

The major weakness of such data systems is the uncertain validity of diagnosis data. This is especially true for claims databases and outpatient data, which are developed to facilitate medical billing. Since these databases are based on billing codes, they do not contain information on other variables that may impact evaluation such as smoking history, occupation, weight, alcohol consumption, etc. Also, outcomes that are poorly defined by the ICD-9 billing system, such as Stevens Johnson, syndrome are difficult to evaluate using these systems. To obtain a complete picture of results from these types of databases, retrieval and review of actual medical records may be indicated, which add time and cost to the study. Also, by definition, such databases only include illnesses severe enough to come to medical attention.

It is very important that—no matter what pharmacoepidemiology methods are used to investigate safety issues—these methods are grounded in good scientific practice. For this reason, the International Society for Pharmacoepidemiology has developed Guidelines for Good Pharmacoepidemiology Practices (GPP) (http://www.pharmacoepi.org/resources/guidelines_08027.cfm). These Guidelines lay out a framework for conducting and evaluating pharmacoepidemiologic studies, promoting sound pharmacoepidemiologic research by encouraging rigorous data collection, analysis and reporting as well as facilitating the appropriate utilization of technical resources by promoting careful study design and planning of study conduct.

As stated above, claims data analysis poses particular challenges in ensuring the validity of results and appropriately interpreting and applying results. In addition, as a science-based regulatory agency, the FDA has responsibility to oversee issues

Wyeth

related to the safety of the products it regulates. For both these reasons, it is important that CMS work closely with the FDA when using claims data analysis for patient safety purposes. This will help ensure that the analysis is valid, interpreted appropriately and communicated responsibly. At the same time, it is important to recognize the distinct roles that FDA and CMS play in the assessment of medical interventions.

Proposed and implemented CMS policies (or other federal agencies) that use these claims data, such as decisions relating to Medicare coverage and payment, should be transparent and specific as to the data used and analysis performed in support of the decision.

Given the complexity of these issues, Wyeth suggests that CMS and other agencies be entirely transparent about the data and analysis used to make policy decisions, particularly those that may inform coverage and payment decisions. In the Proposed Rule, CMS references a number of potential uses of the data that could have profound effects on coverage under either Parts D or B. If the Part D claims information will be used as the basis for coverage and payment decisions, CMS should provide a detailed framework describing the process by which these decisions will be made. This structure should detail:

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

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

Use of Pricing Data

Wyeth believes that the pricing information contained in the Part D claims do not accurately reflect the actual cost of drugs to Medicare drug plans. We

Wyeth

suggest that CMS note the inaccuracy of the claims information and reiterate the confidentiality of actual pricing data.

The Part D claims data include a reported price for a product that ostensibly represents a negotiation between the pharmacy and the plan. However, rebates, discounts, and other negotiated price concessions are not included in the reported price but are included in other reporting performed by the Part D plans. It is not clear whether this rule would apply only to the reported pricing information contained in the Part D claim or if the rule would apply to the other reporting performed by Part D plans. While it may be necessary for government agencies to obtain that information to obtain a complete picture of the costs, CMS should be clear on how the confidentiality protections afforded by law would not be undermined. The preamble states that the proposed revision does not affect the applicability of the Privacy Act or the Trade Secret Act, and it may be that CMS should confirm the Trade Secret Act's applicability to the pricing data.

Conclusion

Wyeth appreciates the opportunity to comment on the Proposed Rule on the use of Medicare claims data. These data can be a useful tool when their limitations are considered carefully and when the research protocols and data use are transparent to responsible public scrutiny. We hope that our comments and recommendations are helpful to CMS as the agency finalizes plans to facilitate the development of this significant dataset. If you have any questions or require additional information, please feel free to contact me.

Sincerely,

Matthew D. Eyles

Matthew D. Eyles

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

Organization : **PhRMA**

Category : **Drug Association**

Issue Areas/Comments

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Sharing Data with Entities Outside of CMS

See attachment

CMS-4119-P-107-Attach-1.PDF

Richard L. Smith
SENIOR VICE PRESIDENT
POLICY, RESEARCH AND STRATEGIC PLANNING

PhRMA

December 18, 2006

Leslie V. Norwalk, Esq.
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, DC 20201

Re: **CMS-4119-P; Comments Regarding Medicare Program; Medicare Part Data, Proposed Rule**

Dear Ms. Norwalk:

The Pharmaceutical Research and Manufacturers of American (PhRMA) is pleased to submit comments on the proposed rule published by the Centers of Medicare and Medicaid Services (CMS) concerning the Secretary's use of claims information, presently being compiled for Part D payment purposes, for other research, analysis, reporting and public health functions.[1] PhRMA is a voluntary nonprofit organization representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, healthier, and more productive lives. PhRMA companies are leading the way in the search for cures.

Our detailed comments on these issues raised by the proposed rule are set out below.

Summary

PhRMA supports CMS' overarching goal of using information to make healthcare more transparent and evidence-based. Better information appropriately applied in support of physician and patient decision-making can contribute to effective, patient-centered solutions to our cost and quality challenges.

Collection and appropriate use of Medicare Part D claims data along with data from Parts A and B of Medicare offers a valuable new resource that, if used well, can

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

help advance the goals of higher quality and value in health care. However, it is critically important that all qualified researchers share access to these data, that analyses relying on Part D data are performed appropriately, that those individual or groups using the data and applying results understand both the strengths and limitations of claims data, and that results of research are appropriately communicated.

Analyses using claims data may in some instances provide a sufficient basis to draw conclusions, but in other instances – particularly when moving from simple descriptive analyses to evaluation of outcomes – will not provide a definitive answer but rather an association between factors or identification of issues for potential additional research. Several factors contribute to these limitations, including inability to control for confounding factors that can influence outcomes, lack of laboratory values and complete diagnostic and medical information, and incomplete or inaccurate documentation of patient encounters.

To promote high quality research, CMS should make Part D claims data broadly available (alone and linked to data from Parts A and B) to qualified external researchers to perform a range of evaluations. Qualified researchers are those who demonstrate the expertise and experience to conduct the proposed evaluation. The agency should make claims data available in ways that are consistent with its statutory authority, comply with patient privacy protections and maintain the confidentiality of trade information.

PhRMA supports appropriate use of Medicare claims data (within the framework outlined above) as part of our broader commitment to evidence-based, patient-centered approaches to improving health care quality and controlling health care costs. Research based on integrated (Part A, B and D) claims data can play a role in examining issues like gaps in quality, the cost of non-adherence to therapy, and the impact of benefit design on the quality and cost of care delivery. At the same time, there are significant limitations in the range of analyses that rely on Medicare claims data alone (for example, in regard to quality assessment, claims data could provide information on performance on some quality measures, such as use of a beta-blocker after a heart attack, but not on others, like control of blood glucose levels in diabetics).

It is particularly important for users of integrated claims data to understand that analysis based on claims data alone frequently will not be sufficient to draw definitive conclusions, and will need to be considered in conjunction with other sources of evidence, such as clinical trial data. Considerable progress still must be made in understanding the best methods for synthesizing and drawing conclusions from these different types of data. These challenges are not insurmountable, but they make it imperative that analysis generated from this initiative be handled in a careful, responsible way.

Successful use of integrated claims data requires identification of appropriate research questions and development of sound, carefully constructed research protocols to

answer them. To ensure successful use of Part D claims data, it will be important for all stakeholders to recognize the challenges and limitations, as well as the strengths, of research using claims data and to take steps to ensure that results are valid and appropriately communicated. There are a number of issues that we would like to raise to support appropriate use of Medicare claims data to meet our pressing health care challenges.

I. Sharing Data with Entities Outside of CMS

PhRMA agrees that, as with currently available data from Parts A and B, claims data resources that combine information from Parts A, B and D could be used "in a similarly constructive manner" by a wide range of qualified external researchers.

As indicated by CMS' publication of a proposed rule and the broad range of research the agency describes, integrated claims data from Parts D, A and B offers a unique new resource. As a result, CMS should develop a guidance document using good guidance practices to update and clarify its policy on release of claims data for research purposes. These revisions will serve to help achieve CMS' goal of ensuring appropriate use of claims data for research to improve knowledge relevant to medical care and public health.

CMS specifically solicits input on the "proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health," and also 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."

All health care stakeholders share responsibility for improving knowledge relevant to the public health, and the research-based pharmaceutical industry is committed to this task. We believe CMS should not seek to define a national research agenda for external researchers interested in using Medicare claims data; rather CMS should approve requests for data on a broad range of legitimate research questions that can expand the evidence base and contribute to improved health care and policy decision-making. With the improvements we are recommending below, we believe existing policy on data use agreements provides a sound basis for release of data and that additional regulatory limitations should not be applied.

PhRMA understands that the Federal government does not want use of federally generated health-related data to focus on commercialization of products. However, this concern should not preclude individuals and organizations in the private sector (e.g., physicians, health insurers, pharmacy benefit managers, pharmacies, and pharmaceutical, medical device and diagnostics manufacturers) from gaining access to such data, when

research has a public health purpose and appropriate steps are taken to safeguard patient privacy. Indeed, CMS currently releases data for research sponsored by manufacturers of a wide range of medical interventions. We note that pharmaceutical research companies invest billions of dollars in clinical and clinically related research annually, virtually all of which is associated with their medicines and the therapeutic areas that they target. This research is routinely accepted by the Federal government and recognized as necessary, unbiased, valid and in the public interest.

Thus, CMS should support the legitimate use of data for analysis by any technically capable party (including manufacturers and other organizations with whom they contract for research), as long as the analysis is deemed scientifically sound, provides knowledge in support of the public health, and is subject to appropriate safeguards (such as data encryption and data use agreement requirements) to protect patient privacy.

If bias is a concern, we note that it is well accepted that all parties – including but not limited to Federal and state government researchers and organization, academics, payers, and other external researchers – have biases including, for example, which research questions they seek to answer. Broader external access to data provides valuables checks and balances to government-sponsored research and will foster development of a broader array of analyses to support stronger public health policies. Arbitrarily denying access to claims data by qualified researchers in any one sector is likely to exacerbate rather than mitigate concerns about bias.

In addition, scientists in the National Institutes of Health and the private sector (such as academic research institutions and pharmaceutical and medical technology companies) share a similar mission of, as described by CMS, "conducting and supporting research regarding the cause, diagnosis, prevention and cure of human diseases." Researchers in both the public and private sectors should have access to Medicare claims data for research in support of this shared mission.

Finally, providing product manufacturers appropriate access to Medicare claims data can enhance patient safety. Indeed, as manufacturers are the only organizations with both detailed knowledge of their products and the regulatory responsibility to develop evidence on its effects, it is particularly important to ensure they have access to such data.

CMS should clarify in its final rule that, subject to appropriate protections for patient privacy and confidential trade information, all qualified external researchers will have equal access to Medicare Part D data (alone, linked to other Medicare data, and/or provided via the Chronic Care Condition Data Warehouse (CCW)) under the same terms. Restrictions on access to data by external researchers should not be based on the type of organization or funding source (whether external researchers are performing government-supported or privately supported analyses) but on the researchers' qualifications, the legitimacy of the research question and the soundness of the research protocol.

To this end, CMS should add the following language in proposed new paragraph (f)(5) of 42 CFR § 423.505 stating:

> *"To the extent such information is released to outside entities, it will be made available to any qualified external researcher for evaluations in the interest of the public health."*

CMS also should include in the regulation language from the preamble that identifies examples of the types of research for which the information will be released, including pharmaceutical impact research, quality improvement and performance, patient adherence, and comparative effectiveness of plans, delivery options, items and services.

Additional sub-regulatory changes to CMS policy on data release:

In addition to modifying the text of the regulation, CMS should update its existing policy on release of files through data use agreements and reissue it as a guidance developed through the agency's good guidance practices. To ensure broad access, CMS should modify its existing policy on release of identifiable data to make clear that requirements apply equally to all qualified external researchers for legitimate research purposes.

In updating its policy on release of data, the agency should delete language in paragraph seven of its "Criteria for Review of Requests for CMS Research Identifiable Data"[2] which currently states: "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." In light of the fact that a) Part D claims data will be used, to evaluate, at least in part, the impact of use of prescription drugs and, b) similar data from Parts A and B already are released to a range of commercial entities, we believe that this criterion is not appropriate. In particular, the current language states that data requests are likely to be denied if the requestor is associated with a ***commercial entity***. As we described earlier in this section, research using claims data from CMS that is funded by commercial entities has advanced, and will continue to advance, knowledge in support of improved health for Medicaid and Medicare beneficiaries. CMS' can appropriately address any concern about the use of data for commercial purposes through review of requests for data rather than prohibiting use by requestors associated with commercial entities. [3]

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[2] "Privacy Protected Data Request: Policies & Procedures," accessed Dec. 4, 2006 at http://www.cms.hhs.gov/privprotecteddata/

[3] While the criteria relates to the Research Identifiable Data and not the more limited data sets, it is the focus on funding and singling out of the pharmaceutical industry as a funder rather than focusing on te purpose of the research that is unwarranted and inappropriate.

In developing guidance on release of data, CMS should more clearly define those types of research uses considered "commercial purposes" for which data requests will be denied. Agency policy should define a narrow set of excluded uses (e.g., use of data to target marketing of medical products to specific providers). In a competitive market-based health system, many uses of claims data that are clearly in the interest of public health also could be misconstrued as research for commercial purposes. For example, research on the comparative effectiveness of various benefit designs or patterns of adherence to needed medications could be viewed as serving the business interests of health plans or other stakeholders. Use of Medicare data to evaluate physician or provider performance on quality measures in support of payment incentives could affect the financial performance of those providers. Outside of the clearly excluded uses (such as targeted marketing), requests for data to answer legitimate research questions of public health interest should generally be granted. If CMS exclusions are too broad in this area, it could chill many types of research in the public health interest.

CMS also should consider updating its policy on data use agreements to more clearly define the criteria the agency will use to evaluate research qualifications. The agency could consider factors such as whether the researcher or organization has: well-documented scientific expertise, a track record of scientific publications in the area to be evaluated in the proposed study, and demonstrated the capability to conduct and complete the proposed study.

Access to limited data set files:

The proposed rule identifies a wide range of potential research uses for linked Medicare claims data that could involve use of data files in the form of limited data sets (LDS) or research identifiable files (RIFs)[4]. We assume that one of the primary forms in which Part D data are made available is a limited data set standard analytic file that includes a Medicare data sample that can be linked to other Medicare data files. We support CMS making available a beneficiary-level sample of Part D data that is linkable across files using encryption that is standardized with other files.

These types of data (both LDS and more robust encrypted data sets like RIFs) are necessary for meaningful longitudinal health research to address patient care and public health issues such as access to care and quality, cost and outcomes of care. Part D claims data at the LDS level and higher levels of data (which are encrypted but subject to CMS Privacy Board review) should be made available to qualified external researchers. CMS policy should clearly describe the processes the agency will use for evaluating release of LDS data sets, which are presumed to be compliant with privacy requirements, and higher-level data sets that require additional agency review to ensure appropriate, timely access to data while safeguarding patient privacy.

[4] Description of available CMS data provided by the agency's Research Data Assistance Center, accessed Dec 4, 2006 at http://www.resdac.umn.edu/

We believe the instances where researchers outside CMS (whether other federal agencies or external researchers) require use of beneficiary-level data that is directly identifiable will be very limited. For example, FDA use of data for pharmacovigilance purposes potentially could involve use of this type of data. We understand that additional restrictions on access to this type of data may be necessary to protect patient privacy. At the same time, it is critically important to ensure that federal rules on use of data for policy decisions that affect specific products or services contain provisions that allow for verification of results by affected third parties such as patient and provider groups and manufacturers.

This issue may require additional rulemaking to clarify procedures for CMS release of this type of data to other federal agencies. We ask the agency to initiate a separate dialogue with affected stakeholders to address operational standards to address this issue.

In addition, in the final rule CMS should clarify the types of files that will be available in the CCW and apply the same policy on access to these data sets that it establishes for access to other data sets. We also urge the agency to make CCW data available in the form of limited data set files that can be released more broadly to external researchers while protecting patient privacy.

We are concerned language in the proposed rule suggests CMS may create separate CCW access standards for different types of external researchers. Specifically, CMS states that it "will specifically address the needs of a segment of external researchers as part of our implementation of section 723 of the MMA..." In developing policy on access to the CCW data, CMS should address the needs of all external researchers in a way that provides equal access to data. For the reasons described above, a policy that creates an uneven playing field by restricting access to Medicare data to a subset of external researchers would be untenable and not in the best interest of advancing knowledge for public health.

Establishing procedures for consistent, appropriate, timely release of data:

CMS should establish procedures for consistent, appropriate, timely release of data. To ensure timely and fair action on data requests CMS should, for external data requests, generally apply a "first in, first reviewed" policy of evaluating requests in the order they are received. We understand that the agency may need to make exceptions to this policy, but should establish it as a general rule.

Peer-review of research prior to publication also is an important element of ensuring high quality research. CMS should require users to indicate whether research was peer reviewed when they release it to the public. In addition, research sponsored by

federal agencies, because it carries the authority of the federal government's imprimatur, should always be subject to peer-review before it is finalized and released to the public.

In addition, for any claims data analyses that are released to the public or applied in public policy decisions, research protocols and data sources must be clearly described. This will help facilitate replication of research and validation of results by other researchers. CMS should include a provision in its policy on release of data stating that when data analyses or reports are made public (whether by government agencies or external researchers), they must include detailed descriptions of the research protocols.

CMS should then make publicly available annual reports on the number of external requests it receives and the timeliness of its action on these requests, and (if it charges a fee for data release) the amounts charged for different types of data and total charges. The reports also should include the number of requests received from different types of entities (e.g., commercial, academic, other federal agency and CMS) and the proportion approved by CMS.

CMS should also consider changes to improve the efficiency and effectiveness of release of data under data use agreements (DUAs). For example, every time a data user wishes to use a particular CMS data file, assuming the DUA has not expired, the user must submit a formal request to CMS for reuse of the data. This entails a new cover letter, order form, DUA, and research protocol. CMS must then review the request and issue a new DUA for the new use of the data. The agency should consider steps to streamline and expedite research involving new uses of data under existing data use agreements.

Several other elements of existing policy on data use agreements help ensure patient privacy is protected and data sets are used for high quality research. These elements should be maintained. These include reviewing requestors expertise to perform the proposed research and reviewing proposed research protocols and data prior to publication.

II. Purpose of CMS Collecting Information

As noted earlier, in the preamble CMS describes a wide range of research that it potentially could perform using integrated Medicare claims data. The preamble to the final regulation also should describe in greater detail how the agency plans to use the results of claims data analyses. In light of the wide range of potential research questions described, methodological challenges of claims data analysis, and limitations on the types of policy questions that can be answered based on this data, it is important for all stakeholders to understand the strengths and limitations of CMS' planned analysis and for CMS to establish uses of its research that are in keeping with accepted research standards.

CMS should ensure processes are in place that are open and transparent and allow for external verification and replication of CMS' sponsored analyses. Specific, explicit procedures should be established to ensure that, if such research informs coverage or payment decisions for specific items and services (whether decisions are made by CMS or its agents under Parts A and B or by private plans under Part D), stakeholders have an opportunity to evaluate the evidentiary basis of proposed decisions and provide input. This should include, where appropriate, open and transparent procedures for development and application of the analyses.

Along with an annual report on processing of external requests, CMS should periodically provide public reports on the government reports and analyses that have been generated using integrated claims data provided by CMS.

CMS also should include in the final rule a description of an open public process for establishing priorities for federally sponsored research using integrated claims data. This process should ensure that there is broad and ongoing dialogue with relevant stakeholders in identifying the highest priorities for research, demonstrations, and evaluations. It also should provide an administrative record so that the rationale for and input on research priorities can be clearly understood.

CMS identifies many potential uses of claims data in the preamble to the proposed rule. In its report *Crossing the Quality Chasm: A New Health System for the 20th Century*[5], the IOM Committee on Quality emphasizes both the importance of a disease-centered approach to improving quality and the systemic nature of gaps in health care quality. "Identifying priority conditions represents a starting point to support the organization of care, bring the evidence base into practice, develop information technology and infrastructure to support care, and develop mechanisms to measure and pay for quality care." The report added that "the system should be designed to optimize care for patients' needs across the entire continuum of care in the most effective and efficient way possible." Appropriate application of Medicare claims data to support a broad, disease-centered research agenda would advance the essential quality improvement goals highlighted by IOM.

Use of integrated Medicare claims data by a wide range of government and non-government researchers can help meet the goal of significantly improving quality in health care by:

- Recognizing growing disease prevalence as a fundamental health care challenge;
- Recognizing that, in both human and fiscal terms, we cannot afford poor quality in health care;
- Supporting a shift beyond silo health care perspectives to achieve transformational improvements in health care quality;

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[5] *Crossing the Quality Chasm: A New Health System for the 21st Century*, Institute of Medicine, Washington, D.C.: National Academy Press, 2001

- Building upon existing research to help address knowledge gaps[6];
- Examining the entire continuum of care and full spectrum of modern medical treatment, and the range of administrative processes, utilization management tools, benefit design, and patterns of care delivery;

In addition, research based on integrated claims data can potentially be used to help answer questions in a range of areas specific to pharmaceuticals. CMS identifies a number of these research areas in the proposed rule. As with any research based on administrative data, it is important to ensure that the research question being asked can be answered by administrative data and that the appropriate methods are employed in conducting the research. As stated earlier, in many instances analysis based on claims data may, when appropriately designed and performed, provide useful information but not definitive conclusions. Potential pharmaceutical-specific areas of research could include:

- Extent to which Medicare beneficiaries receive medicines according to evidence-based guidelines and quality indicators;
- Avoidance of contraindicated medicines and other patient safety issues;
- Extent to which beneficiaries are adhering to prescribed therapy, and if not, the clinical and economic impact of non-adherence;
- The relationship between various arrangements for delivery of pharmaceutical care and provision of care according to evidence-based guidelines and patient adherence to prescribed therapy regimens;
- The impact of medical therapy management programs mandated under the new Medicare prescription drug benefit.

Patient safety:

Integrated claims data can also be used to provide information on a range of safety-related questions. The broad range of issues related to patient safety should be recognized and included in this area of work, including patient safety in different care settings and in use of different medical technologies.

In connection with medicines and other medical technologies, use of claims data should extend beyond examination of unanticipated adverse events. While this is an important aspect of patient safety, other aspects of safety are equally important and, in some cases, may be more readily examined with claims data. These should include reducing non-compliance with pharmacotherapy, avoidance of contraindicated drugs and dangerous drug-drug interactions, and "errors of omission" in medication use.

Use of claims data to examine potential safety issues presents some important challenges, such as the possibility of identifying "false positive" signals that incorrectly associate a safety problem with a particular intervention, interpreting and communicating

[6] Cite to Wennberg, AJMC, etc.

valid findings in the context of other findings, and recognizing the overall risk/benefit balance in which the findings must be viewed.

As stated above, claims data analysis poses particular challenges in ensuring the validity of results and appropriately interpreting and applying results. In addition, FDA as a science-based regulatory agency has responsibility to oversee issues related to the safety of the products it regulates. For both these reasons, it is critically important to ensure that FDA plays a central role in any use of claims data for safety evaluations. This will help ensure that the analysis is valid, interpreted appropriately and communicated responsibly.

Challenges and limitations of claims data analysis:

Analyses using claims data in some instances may provide a sufficient basis to draw conclusions, but in other instances will not provide a definitive answer but rather an association between factors or identification of issues for potential additional research.

The challenges become greater when seeking to use administrative claims data to compare the outcomes of different health interventions. As stated by the Office of Technology Assessment in a 1994 report, the use of administrative databases "to compare the database-derived outcomes of apparently similar patients undergoing alternative treatments...raises more serious issues" than simpler descriptive analyses.[7]
Specific factors that CMS and stakeholders should consider when using administrative data include the following:

- Lack of randomization and, therefore, inability to control for confounding factors that influence patient outcomes, such as selection bias. This is also a challenge for inferring causality between receipt of a service or healthcare technology and outcomes experienced by the patient, such as hospitalizations or mortality.

- Lack of laboratory values and complete diagnostic and medical data. Diagnostic codes used in claims data often are used for procedures to rule out a diagnosis. In addition, because claims data do not include results of diagnostic testing and information in the medical record, such data can not by themselves provide a complete picture of beneficiary health status.

- Potential problems with administrative claims data due to incomplete or inaccurate documentation of patient encounters. Often there is little incentive to accurately document the patient encounter unless documentation is required for payment. This is especially the case in settings of care that receive a bundled

[7] *Identifying Health Technologies That Work: Searching for Evidence*, Office of Technology Assessment, OTA-H-608, September 1994

payment for a patient's care. Without proper incentives, administrative claims may suffer from inaccuracies and a high prevalence of missing data.

- Lack of clinical and health outcomes data that accurately and appropriately capture the experience of the patient. At this time, claims data does not contain the richness of information needed to accurately portray the experience of the patient. Some recent examples of CMS' attempt to enhance their claims data include the recent oncology demonstration to collect information on nausea, fatigue, and pain from cancer patients. Efforts such as these which provide additional payments to physicians should continue to be encouraged. The growing prevalence of electronic health records (EHRs) should also enhance information on true patient experience.

- Building episodes of care that fully encompass the patient experience. Although there has been some improvement in developing episodes of illness algorithms, there are many challenges still associated with fully understanding a patient's care experience.

Statistical methods to control confounding of results continue to be challenging to the analysis of claims data regardless of recent advancements in statistical methods such as instrumental variable analysis and propensity scoring.

These and other issues bear careful consideration as CMS considers approaches to foster wider use of research based on Medicare claims data. Several useful documents could be used to help address methodological issues, including the Good Pharmacoepidemiology Practices published by the International Society of Pharmacoepidemiology (ISPE) and the Checklist For Retrospective Database Studies developed by the International Society for Pharmacoeconomics and Outcomes Research's (ISPOR) Task Force On Retrospective Databases.

In light of these limitations, we are concerned that several statements in the preamble may overstate the potential for claims data analysis. For example:

- On p. 61447, CMS states: "Part D claims data are needed for these budget neutrality calculations as well as quality measures assessing appropriate use of medications." As noted earlier, while claims data can play a role in this area, in many instances it will be very difficult to make determinations about outcomes, medical quality or appropriate use of medications from claims data, even when Part D information is integrated with claims data from Parts A and B. Integrating claims data with laboratory can enhance researchers' ability to evaluate the quality of medical care for some conditions (e.g., hyperlipidemia) that have well-established surrogate endpoints that equate to clinical effectiveness, but not for many other conditions where no such marker exists.

- On page 61451, the preamble says: "Because drug usages can be used as a surrogate measure for the existence and severity of diseases, Medicare Part D data could be used to investigate the incidence..." Again, this may be true in some carefully circumscribed situations. However, in other instances this will not be the case, since physicians often prescribe pharmaceuticals for uses that are medically appropriate but outside of those uses described in FDA-approved labeling (so-called "off label" uses). This example illustrates the importance of ensuring that mechanisms are in place for external replication and verification of research using data from the CCW.

- In connection with the use of data in the CCW (page 61452), CMS says: "Researchers would be able to receive a complete picture of a beneficiary's care, and determine whether the treatment of chronically ill beneficiaries (including Parts A, B and D treatment) is as effective and efficient as possible." While the CCW certainly will provide a powerful new research tool that allows for disease-specific longitudinal research through integrated claims data, this statement suggests that claims data alone can provide a complete picture of beneficiary care, which is not the case because it does not include all information such as the patient's laboratory or medical records. Research based on CCW claims data that assumes a complete picture of beneficiary care could result in inaccurate findings that undermine the public health. Providing equal access to CCW data sets for external researchers will help ensure that this does not occur.

CMS requests comment on limitations on data when shared for purposes other than fulfilling CMS's responsibility to administer the Part D program. We believe CMS should not establish separate policies based on this distinction. Except for safety assessments under FDA purview (pharmacovigilance), CMS's responsibility to administer the Part D program encompasses many if not all of the legitimate research questions of interest to external researchers (such as questions related to access to care, quality of care and clinical outcomes for beneficiaries in the Medicare program). Thus, the distinction will not be a meaningful one to make in the regulation.

III. Applicability

The proposed rule amends the contracting provisions of the Part D rule to allow CMS to collect "claims data and other related information." It is not clear how broad the phrase "related information" is intended to be, and CMS in the final rule should define what related information is intended to cover. The preamble discusses a variety of different studies that might be useful with Part D data but then only discusses the 37 items collected under the prescription drug event data reporting. MMA and other law protects other data that CMS might collect from disclosure and CMS' authority for the data collection under Section 1860D-12 should not alter those protections. For example, certain pricing data that is collected by CMS is protected from further disclosure under Social Security Act (SSA) Section 1927(b)(3)(D). The preamble states that CMS'

proposal if adopted, will not affect the applicability of the Privacy Act or the Trade Secret Act. CMS should confirm the Trade Secret Act's applicability to the pricing data, that "related information" will not include pricing data which is protected by these various other laws and that such data will not be disclosed pursuant to the authority on which this rule is based.

IV. Limitations

CMS states in the preamble that it is issuing the proposed rule "to resolve statutory ambiguity" around its authority to use claims data for purposes other than payment. Claims data is currently collected for payment purposes. SSA, Section 1860D-15 limits the data collected pursuant to that section (relating to subsidy, reinsurance, and risk corridor payments to Part D plans) to purposes related to that section, i.e., payment.[8] In the proposed rule, CMS argues that it has the authority to collect data that it finds "necessary and appropriate" from plans under SSA, Section 1860D-12. That section incorporates a number of Part D Medicare Advantage contracting requirements which include authority to collect data without the limits of Section 1860D-15. If CMS may invoke this independent authority to collect and use data without those limits, then CMS should explain its understanding of the purpose of the limits in Section 1860D-15 and how that purpose will still be given effect. The MMA includes other provisions with disclosure limitations, e.g., the limitation on disclosure of aggregate rebate information under SSA, Sections 1860D-2(d)(2) and 1927(b)(3)(D). Unlike the limitations contained in Section 1860D-15, the confidentiality of the aggregate rebate information is not tied to a particular provision, i.e., by its terms, the disclosure prohibition applies irrespective of whether CMS collects the data under Section 1860D-15 or Section 1860D-12. CMS should confirm that Section 1860D-12 will not be used to alter the effect of other statutory provisions (outside SSA 1860D-15) that circumscribe the use or disclosure of Part D data.

Conclusion

In summary, PhRMA supports broad and equal access to integrated claims data to support a wide range of legitimate analyses to generate knowledge of relevance to the public health. We believe such data can be useful in improving the quality and value of health care provided to Medicare beneficiaries and other patients. In order to achieve this goal, PhRMA believes that the final rule should clarify and more completely address several issues:

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[8] Section 1860D-15(d)(2)(A) provides that payments to Part D plans are conditioned on the plan furnishing CMS with "such information as may be required to carry out this section"; 1860D-15(d)(2)(B) then provides that "[i]nformation disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of [HHS] only for the purpose of, and to the extent necessary in, carrying out this section." Virtually identical language appears at 1860D-15(f)(2).

- First, all qualified external researchers should have access to Medicare claims data for legitimate research purposes. This will support the goal of improving public health by allowing replication and validation of results by multiple and varied researchers. PhRMA further believes that such access can be provided in a manner that is consistent with CMS' concern that the data not be used to commercialize products. The agency should engage in a broader dialogue with stakeholders to ensure its policy balances the need for appropriate access to data with the need to protect patient privacy and data confidentiality.

- Second, CMS should ensure that claims data users within and outside the federal government recognize the strengths and limitations of such data when conducting analyses and communicating results.

- Third, CMS should take steps to improve its policy on release of Medicare data for research purposes. The agency should develop a guidance document to define its policy on release of data, which should include provisions ensure release of research protocols when analyses and reports are made public. The agency also should ensure that studies and analyses sponsored by federal agencies are subject to peer-review before they are made public.

- In addition, CMS should establish clear, open procedures when it or other federal agencies use Medicare claims data to inform policy decisions on specific items or services.

- Finally, PhRMA believes that clarification regarding the Proposed Rule's compliance with certain laws, the reach of the data collection, as well as its statutory basis, would further support CMS' use and disclosure of the data.

We appreciate your consideration of these comments, and we look forward to working with the agency in this important area. If you have any questions, please feel free to contact me at 202-835-3400.

Sincerely,

Richard I. Smith

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

Organization :

Category : **Health Plan or Association**

Issue Areas/Comments

GENERAL

GENERAL

See Attachment

CMS-4119-P-108-Attach-1.DOC

CMS-4119-P-108-Attach-2.DOC

Comments Provided in Response to Proposed Rule – Using Part D Claims Data for Research & Quality Initiatives

Based on our own experience with the Part D data, our thoughts immediately focused on protection of the data when dealing with third parties, and potential misuse of the data by commercial entities.

This "data warehouse" would create a comprehensive data source that could link prescription drug claims to hospitalization, medical office visits, labwork, etc. It could be extremely helpful for post-market surveillance of adverse reactions to new drugs, to see whether adherence to evidence based guidelines impacts the progression of illness and medical costs, and countless other quality improvement projects.

While this proposal addresses outside researchers, it says nothing about the QIOs. Obviously, this proposal needs to include them as recipients of this data for quality improvement projects at the state level. From a Humana perspective, this will be highly preferable to producing CD Roms quarterly, or fighting the battle for secure FTP connections. While Humana's current willingness to share data with the QIOs is a big plus, the greater good would be served by having ALL Medicare data readily available to the QIOs for these projects.

As CMS is accustomed to working with outside researchers, the handling of this data should be subject to the same standards of privacy as any other PHI. This data is not any "more or less private" than other information. Another question is whether, as a Plan, we would be able to view our own data through this warehouse so that we could see our performance against clinical guidelines etc.

We would want to make sure that MTM service data goes into this "data warehouse" so that researchers (including the QIOs) can look specifically at the effectiveness of MTM in achieving key clinical outcomes.