PROPOSED US MEDICARE RULING FOR USE OF DRUG CLAIMS INFORMATION FOR OUTCOMES RESEARCH, PROGRAM ANALYSIS & REPORTING AND PUBLIC FUNCTIONS

The information listed below is Sections B of the proposed ruling on Medicare Part D Data from the Centers for Medicare & Medicaid Services, Department of Health and Human Services, United States government. This information was reformatted for clarity. The proposed ruling would allow use of claims information that is now collected for Part D payment purposes to be used for other research, analysis, reporting, and public health functions. The entire proposed ruling can be found at: http://a257.g.akamaitech.net/7/257/2422/01jan20061800/edocket.access.gpo.gov/2006/06-8750.htm

B. Purpose of CMS Collecting Information

We need to use Medicare Part D prescription drug related data for a wide variety of statutory and other purposes including—

1) Reporting to the Congress and the public on the overall statistics associated with the operation of the Medicare prescription drug benefit;

2) Conducting evaluations of the Medicare program;

3) Making legislative proposals with respect to the programs we administer, including the Medicare, Medicaid, and the State Children's Health Insurance Program; and

4) Conducting demonstration projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.

When the Congress passed the MMA in December 2003, allowing coverage of outpatient prescription drugs under the new Medicare Part D benefit, this addition, we believe, was the most fundamental change to the Medicare program since its inception in 1965. With this fundamental change to the program, it is critical that the Secretary maintain the ability to evaluate and oversee the progress of the new benefit and how it affects other parts of the Medicare, Medicaid, and State Children's Health Insurance programs.

We have discussed in a variety of public settings, including an open door forum on this topic in the summer of 2005, the critical importance of the new Medicare Part D prescription drug event data—hereafter referred to as "claims" data—for studies on the impact of drug coverage on Medicare beneficiaries, spending for other Medicare health care services, efforts to improve the quality of health care services for Medicare beneficiaries with chronic illnesses, efforts to address health disparities by understanding how drugs are being used and how well they work in minority populations and in other populations which are often not studied in clinical trials (for example, older patients, patients with multiple co-morbid diseases, people with a disability), providing protection against adverse drug events through effective post-market surveillance on the safety of drugs for Medicare beneficiaries, and other studies to improve public health. Part D claims data must be linked at the individual beneficiary level to Parts A and B claims data to facilitate these studies. Individually identifiable data are required to link data across files, over time and to conduct multivariate analyses. As we discuss in greater detail in section II.C.2 of this preamble, CMS is developing a chronic care database that will link these Medicare Parts A, B, and D claims at the beneficiary level. This database will be an important new tool to facilitate our research, on a wide variety of topics that focus on improving the quality of and reducing the cost of health care services.

As discussed in greater detail in section II.C. of this preamble, we believe that when information is collected under the auspices of section 1860D-12(b)(3)(D) of the Act, the restrictions of section 1860D-15 of the Act would not apply to such collections. Thus, any information collected for Part D purposes under this proposed rule would no longer be subject to the section 1860D-15 of Act limitations and could be shared outside of CMS as appropriate. Thus, for example, to the extent otherwise permitted by law, we would be...
able to share the data we collect under section 1860D-12(b)(3)(D) of the Act with entities outside of CMS including, for example, the Food and Drug Administration (in order to oversee the safety and effectiveness of prescription drugs and conduct post-market surveillance), as well as the Agency for Healthcare Quality and Research (AHRQ), in order to analyze comparative clinical effectiveness. Moreover, when we share such data, we do not believe any restrictions included in section 1860D-15 of the Act would apply.

In section II.C. of this preamble, we provide a detailed explanation of a number of purposes for which the Part D data collected under the section 1860D-12(b)(3)(D) authority would be used. We also request comments on whether there should be any limitations on data when shared for purposes other than fulfilling CMS's responsibility to administer the Part D program.

1. Public Reporting (Proposed Sec. 423.505(b)(8) and(f)(3)(i))

We believe we need the Part D claims information in order to report to the Congress and the public on overall statistics associated with the Part D program. For example, we need to preserve the ability to report on the performance of the Part D benefit program. We note that Congress specifically amended title XVIII of the Act to address reporting on all aspects of that title, including Part D. We anticipate we may wish to report statistics on issues such as the experience of Medicaid beneficiaries as their pharmacy coverage changes from the Medicaid to the Medicare program. In order to analyze this information, we will need to have access to identifying beneficiary information (such as HIC number), information about the drug dispensed (including NDC, quantity and days supply), information about the amount paid by the beneficiary (including amounts paid on the claim, reimbursed by third parties, counting toward TROOP, low-income cost sharing subsidy, amount paid for standard benefits, and amount paid for non standard benefits). We anticipate potentially using this information to report statistics to Congress or the public or both with respect to the drug utilization of this unique population and whether they continue to receive the same mix of prescriptions as previously. We might also use such information to evaluate and report on this population's cost-sharing and whether there were any changes in their out-of-pocket costs vis-a-vis Medicaid coverage of prescription drugs.

Section 101(e) of the MMA specifically extended the study authority in section 1875(b) to include the prescription drug program under Title XVIII. Section 1875 now states in pertinent part that the Secretary "shall make a continuing study of the operation and administration of this title * * * and shall transmit to the Congress annually a report concerning the operation of such programs."

Another example of an issue on which we may want to report would include Medicare beneficiary utilization under the new drug benefit by class of drug. For example, we may want to report statistics on what classes of drugs are most utilized by the Medicare population, and whether there has been variation in such utilization across gender, age, and year. This would require access to such information as HIC number, date of birth and gender, date of service, and information about the drug itself (such as NDC, quantity and supply).

We may also want to include in its national program statistics publications information about the Part D program that would require drug claims data. Such statistics include aggregate Medicare and beneficiary spending by class of drug, the total number of prescriptions by class of drug, average beneficiary cost-sharing amounts, catastrophic coverage utilization, geographic variation in utilization and pricing, third party payers paying on behalf of beneficiaries, whether drugs being dispensed are covered by plans, the average number of drugs used by beneficiaries, and other similar statistics. In order for us to be able to produce these types of program statistics, the following claims information are necessary:

1) Ingredient cost of the product dispensed.
2) Dispensing fee paid.
3) Sales tax.
4) Amount paid on the claim that is both below and above the catastrophic coverage threshold.
5) Amount paid by a patient and not reimbursed by a third party.
6) Amount of third party payment that would count toward a beneficiary's out-of-pocket costs in meeting the catastrophic threshold.
7) Low income cost sharing subsidy amount, if any.
8) Reduction in patient liability due to other payers paying on behalf of the beneficiary.
9) Amount paid by the plan for standard benefits.
10) Amount paid by the plan for nonstandard benefits.
11) Identification of coverage status.
12) Identification of dispensed product using the national drug code number.
13) Identification of whether the drug was compounded or mixed.
14) Identification of prescriber's instruction regarding substitution of generic equivalents or order to `dispense as written'.
15) Quantity dispensed.
16) Days supply.
17) Fill number.
18) Dispensing status and whether the full quantity is dispensed at one time, or the quantity is partially filled; (for example, to calculate utilization by drug classes).
19) Health insurance claim number—
   ++ Patient date of birth and gender,
   ++ Identification of whether unique pricing rules apply; and
   ++ Identification of whether a beneficiary has triggered the catastrophic threshold (for example, to calculate average beneficiary cost-sharing, amounts and average number of drugs purchased).

2. Evaluations of the Medicare Program (Proposed Sec. 423.505(b)(8)and(f)(3)(ii))

We also anticipate that we would need to collect prescription drug claims information in order to conduct evaluations of the Medicare prescription drug program, including evaluations and oversight of the plans themselves. For example, we anticipate that in some cases, in order to evaluate the effectiveness of a plan's utilization management techniques we may need access to the claims information for a particular plan. For example, we have already announced on our Web site in frequently asked question 4483, (http://questions.cms.hhs.gov/), that in certain cases, plans could cover over-the-counter medications as part of a cost-reduction strategy. We stated that in certain cases nonprescription drugs (for example, Prilosec OTC[supreg] and Claritin[supreg]) were available by prescription when first marketed. Once off-prescription, these products may offer significantly less expensive alternatives to branded prescription medications, and work just as well for most patients. Therefore stated that plans could provide such over-the-counter drugs as part of a cost-effective drug utilization management (for example, step therapy) program. In cases where a plan offered coverage of such over-the-counter drugs, we wish to preserve the ability to monitor whether:

1) The over-the-counter drugs are in fact being accessed and
2) Whether it appears the step-therapy is saving money.

Such evaluation, we believe, would require access to information on the claim identifying the Part D sponsor and plan, information with respect to the drug prescribed, as well as information about beneficiary and plan payment. In this way we would be able to compare the amount spent on the over-the-counter drug against what would have been spent if a beneficiary had utilized a prescription drug on the plan's formulary. We would likely need to review alternatives to the nonprescription drug and determine the average plan payments for such nonprescription drugs. We believe we would need to aggregate such information to determine whether the plan decreased its overall spending by offering the step-therapy protocol.
Furthermore, in order for us to evaluate the Medicare program overall, 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. It will be important to determine how the Part D benefit affects these programs. 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. In order to evaluate the effect of Part D on Part C and other programs' spending, we would likely need to evaluate aggregated and nonaggregated claims data, including elements relating to health insurance claim number, date of service, date of birth, gender, the drug dispensed, its quantity, whether it was compounded or mixed and other information relating to the drug coverage received by the beneficiary.

3. Legislative Proposals

We also believe that we would need to collect claims data to support legislative proposals offered to Congress relating to programs administered by CMS, including the Medicare, Medicaid and State Children's Health Insurance programs. Claims information could be used to derive statistics that would illustrate why certain changes to the Medicare statute should be considered, or why certain research and demonstration projects should be funded. For example, if we were to develop a proposal to move coverage of some drugs now covered under Part B to Part D or vice versa, we would need access to claims data to derive statistics to assess the cost impact of such a proposal.

Thus, we would likely need to access claims data relating to the drug dispensed as well as the cost incurred under Part D. To analyze the cost incurred under Part D, we would need to see the amount paid by the plan (for example, ingredient cost, dispensing fee and sales tax) as well as whether we were required to pay reinsurance on the claim (for example, amount incurred above and below catastrophic), whether we paid a low income subsidy for the claim, the amount of beneficiary cost sharing, whether the drug was part of a basic supplemental benefit, and whether the drug was covered by the plan. This would allow us to assess costs involved with moving coverage from one part of the program to another.

4. Demonstration Projects and Research Studies

We would also need the various elements of the Part D claims data to conduct demonstration projects and make recommendations for improving the economy, efficiency, or effectiveness of the Medicare program. Conducting demonstration projects and making recommendations for improving the Medicare program based on the evaluation of the effect of prescription drug coverage on health outcomes, safety or Medicare spending should positively affect patient care and provider satisfaction, as well as aid us in administering the various programs under our charge.

Below, we describe the categories of data elements on the prescription drug claims and explain why our studies and projects require collection of such elements. It is also important to note that this proposed rule would permit retrospective studies of the administrative records (prescription drug event data) of Part D services for analysis after the services have already been provided. As such, research using Part D claims data is not comparable to clinical trials which are more prospective in nature and involve patients who may have access to certain drugs and other patients who may not have access to those drugs. We note that while we currently have studies underway that will require these collections, we anticipate that other similar studies will be conducted in the future that would also require collections of the data elements included on the Part D claims.

An illustrative list of the studies currently underway is attached to this proposed rule as Appendix A. The categories of these elements are as follows:
a) Drug Plan Identifiers (Such as the Part D Sponsor and Benefit Package Identifier)

In our follow-up analysis on beneficiaries who participated in the replacement drug demonstration (section 641 of the MMA), we will be evaluating how enrollment in Part D affects the cost sharing and utilization of these beneficiaries. We would need plan identifiers in order to compare how utilization and cost sharing of this population varies plan by plan and to analyze such variation according to the design of the plan selected. Without plan identifiers, we could not tie particular cost sharing or utilization to a plan and determine whether certain plan design features minimized beneficiary cost-sharing. Moreover, in evaluating other managed care and fee for service demonstrations, we will sometimes need plan identifiers in order to compare enrollees in demonstration plans to enrollees in other MA plans and fee-for-service beneficiaries in the same geographic area. Drug plan identifiers will assist in matching beneficiaries to specific Part D prescription plan coverage.

b) Beneficiary Identifiers (Such as Health Insurance Claim Number, Date of Birth, and Gender)

Our current and future research, demonstration and evaluation projects will require collection of beneficiary identifiers in order to link Part D claims with Parts A and B claims at the beneficiary level. For example, in order to link Parts A and B data with Part D claims data, we would need to know the beneficiary's HIC number, name, and date of birth, in order to match claims appropriately. Once the data are linked they will be used in studies that evaluate drug utilization and its impact on other health care services, studies that measure the impact of the new drug benefit on improvements to beneficiary access to needed medications, and studies that link beneficiary characteristics, for example, age, race, sex, with drug data.

For example, in the Medicare chronic condition data warehouse, we will use beneficiary identifiers such as HIC number, name, age, race and sex, in order to develop the public database under section 723 of the MMA which links data at the beneficiary level. The purpose of the database is to permit studies of chronic illness in the Medicare population to improve quality of health care and reduce the cost of health care services. Similarly, in all of our demonstration projects that use Part D claims data as part of the budget neutrality test, beneficiary identifiers are needed to link Parts A, B, and D claims data to examine the total cost of the demonstration intervention group compared to the control group.

c) Information About the Drug Dispensed (Such as NDC Code, Days Supply, Quantity, Generic Identification, Compounding, Refills, and Dispensing Status)

We are engaged in a number of projects and studies which will require collection of information with respect to the specific drug that is dispensed to enrollees. For example, in the mandated chiropractic demonstration (section 651 of the MMA), we will need to collect information on the drug dispensed to determine whether the use of chiropractic services reduces the use of pain medication. The purpose of the demonstration is to test whether the expanded coverage of chiropractic services results in offsetting decreases in other covered services such as pain medications, since the demonstration is required to be budget neutral. Therefore, we will need to study the use of pain medications in the demonstration and control groups to determine if the demonstration appears to be causing a reduction in the use of pain medications.

We will also use drug dispensed in the Chronic Condition Warehouse (section 723 of the MMA) to refine identification of beneficiaries with chronic conditions (for example, insulin use and diabetes), to facilitate analysis of medication usage for beneficiaries with chronic illness, and to analyze the effectiveness of different treatment modalities. We also anticipate that we will engage in future studies and analyses that measure and examine quality of services or patient outcomes by utilization of certain types of medication. For example, we may conduct a study to determine whether access to beta blockers reduces the risk of heart attacks.
In addition, we may perform studies that examine medication adherence and persistence patterns, which in turn can be used as control factors in outcomes research or to examine, for example, how specific medication therapy management programs under Part D affected medication adherence and persistence.

d) **Prescriber Identification**

We need to know who prescribed the drug for studies that assess appropriate prescribing practices such as those that would link physician payment to quality measures. We are exploring value-based purchasing initiatives, in which we may collect data on the extent to which physicians are appropriately prescribing needed medications.

e) **Payment Amounts**

We need to know payment amounts, including dispensing fee, amount paid below and above the catastrophic threshold, amount paid by patient and other third parties, sales tax, and low income subsidies for a variety of studies that assess the impact of the drug benefit on beneficiary cost-sharing, Medicare program payments, and total drug spending. In our demonstration evaluations, including disease management, physician group practice, chiropractor, and follow-up on the Medicare replacement drug demonstration, we will analyze the impact of the demonstration interventions on drug spending and utilization as well as total Medicare spending. Because these analyses often disaggregate the treatment group beneficiaries into categories based on characteristics identified as the analysis is underway (for example, source of referral into demonstration, disease, length of time in demonstration, interval between hospitalization and entry into demonstration, etc.), claims detail needs to be retained at the patient level so they can be included in any group or subgroup analysis into which a particular beneficiary falls in order to determine aggregate cost statistics for the particular grouping.

We propose to revise Sec. 423.505(b)(8) by clarifying that Part D plan sponsors must comply with the disclosure and reporting requirements set forth by Sec. 423.505(f). Furthermore, we propose to add a new Sec. 423.505(f)(3) which would specify that, as part of the existing information disclosure, we would access the drug claims and related information that is already submitted to CMS for purposes the Secretary deems necessary and appropriate. These purposes would include, but not be limited to--

1) Reporting to the Congress and the public or both on overall statistics associated with the operation of the Medicare prescription drug program;
2) Conducting evaluations of the overall Medicare program, including the interaction between prescription drug coverage under Part D of title XVIII of the Act and the services and utilization under Parts A, B, and C of title XVIII of the Act, titles XIX, and XXI of the Act;
3) Making legislative proposals to the Congress regarding Federal health care programs and related programs;
4) Conducting demonstration projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.