exchanges of property for an annuity contract (other than an annuity contract that either is a debt instrument subject to sections 1271 through 1275, or is received from a charitable organization in a bargain sale governed by § 1.1011–2) after October 18, 2006.

(ii) This paragraph (j) is effective for exchanges of property for an annuity contract (other than an annuity contract that either is a debt instrument subject to sections 1271 through 1275, or is received from a charitable organization in a bargain sale governed by § 1.1011–2) after April 18, 2006 if the following conditions are met—

(A) The issuer of the annuity contract is an individual;

(B) The obligations under the annuity contract are not secured, either directly or indirectly; and

(C) The property transferred in exchange for the annuity contract is not subsequently sold or otherwise disposed of by the transferee during the two-year period beginning on the date of the exchange. For purposes of this provision, a disposition includes without limitation a transfer to a trust (whether a grantor trust, a revocable trust, or any other trust) or to any other entity even if solely owned by the transferor.

Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

[FR Doc. E6–17301 Filed 10–17–06; 8:45 am]

BILLING CODE 4830–01–P

GENERAL SERVICES ADMINISTRATION

41 CFR Part 102–35

[FMR Case 2004–102–1; Docket 2006–0001; Sequence 3]

RIN 3090–AH93

Federal Management Regulation; Disposition of Personal Property

AGENCY: Office of Governmentwide Policy, General Services Administration (GSA).

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The General Services Administration is reopening the comment period for the subject proposed rule. The proposed rule pertains to amending the Federal Management Regulation (FMR) by revising coverage on personal property and moving it into Subchapter B of the FMR. A proposed rule was published in the **Federal Register** on September 12, 2006 (71 FR 53646).

DATES: Interested parties should submit comments in writing on or before November 17, 2006 to be considered in the formulation of a final rule.

ADDRESSES: Submit comments identified by FMR case 2004–102–1 by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Search for any document by first selecting the proper document types and selecting ''General Services Administration'' as the agency of choice. At the ''Keyword'' prompt, type in the FMR case number (for example, FMR Case 2006–102–1) and click on the ''Submit'' button. You may also search for any document by clicking on the ''Advanced search/document search'' tab at the top of the screen, selecting from the agency field ''General Services Administration'', and typing the FMR case number in the keyword field. Select the ''Submit'' button.
- Fax: 202–501–4067.
- Mail: General Services Administration, Regulatory Secretariat (VIR), 1800 F Street, NW., Room 4035, ATTN: Laurieann Duarte, Washington, DC 20405.

Instructions: Please submit comments only and cite FMR case 2004–102–1 in all correspondence related to this case. All comments received will be posted without change to *http://www.regulations.gov*, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Holcombe, Office of Governmentwide Policy, Personal Property Management Policy, at (202) 501–3828, or e-mail at *robert.holcombe@gsa.gov*, for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at (202) 501–4755, Room 4035, GS Building, Washington, DC, 20405. Please cite FMR case 2004–102–1.

Dated: October 12, 2006.

Russ H. Pentz,

Assistant Deputy Associate Administrator.

[FR Doc. E6–17340 Filed 10–17–06; 8:45 am]

BILLING CODE 6820–14–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 423

[CMS–4119–P]

RIN # 0938–AO58

Medicare Program; Medicare Part D Data

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would allow the Secretary to use the claims information that is now being collected for Part D payment purposes for other research, analysis, reporting, and public health functions. The Secretary needs to use this data because other publicly available data are not, in and of themselves, sufficient for the studies and operations that the Secretary needs to undertake as part of the Department of Health and Human Service's obligation to oversee the Medicare program, protect the public health, and respond to Congressional mandates.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 18, 2006.

ADDRESSES: In commenting, please refer to file code CMS–4119–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address *only:* Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4119–P, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address *only:* Centers for Medicare &

Medicaid Services, Department of Health and Human Services, Attention: CMS–4119–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Alissa DeBoy, (410) 786–6041; Nancy DeLew, (202) 690–7351.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–4119–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking*. Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

I. Background

A. Introduction

Under the Social Security Act (the Act), the Secretary has the authority to include in Part D sponsor contracts any terms or conditions the Secretary deems necessary and appropriate, including requiring the organization to provide the Secretary with such information as the Secretary may find necessary and appropriate. (*See* section 1857(e)(1) of the Act as incorporated into Part D through section 1860D–12(b)(3)(D) of the Act.)

We propose to implement section 1860D–12(b)(3)(D) of the Act to allow the Secretary to collect the same claims information now collected under the authority of section 1860D–15 of the Act for research, internal analysis, oversight, and public health purposes. While the purposes underlying such collection are discussed in more detail under this proposed rule, they include evaluating the new prescription drug benefit, including its effectiveness and impact on health outcomes, performing Congressionally mandated or other demonstration projects and studies, reporting to Congress and the public regarding expenditures and other statistics involving the new Medicare prescription drug benefit, studying and reporting on the Medicare program as a whole, and creating a research resource for the evaluation of utilization and outcomes associated with the use of prescription drugs.

We note that because this proposed rule would apply to all Part D sponsors, it would apply to any entity offering a Part D plan, including both prescription drug plan sponsors and Medicare Advantage organizations offering qualified prescription drug coverage. We further note that the Part D prescription drug event payment data (hereinafter referred to as ''claims data'') will include data relating to any covered Part D drug, which per 42 CFR 423.100, includes not only drugs, but insulin, biologic products, certain medical supplies and vaccines.

B. Statutory Basis

On December 8, 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Title I of the MMA amended the Act to establish a new Part D in title XVIII of the Act and established a new voluntary prescription drug benefit program. As we stated in the preamble to the January 28, 2005 final rule (70 FR 4197), implementing the new prescription drug benefit, we believe that the addition of outpatient prescription drug coverage to the Medicare program is the most significant change to the Medicare program since its inception in 1965.

Unlike Parts A and B of the Medicare program, where Medicare acts as the payer and insurer and generally pays for items and services on a fee-for-service basis, the prescription drug benefit is based on a private market model. Under this model, CMS contracts with private entities—prescription drug plans (PDPs), Medicare Advantage (MA) plans, as well as other types of Medicare health plans—who then act as the payers and insurers for prescription drug benefits. These private entities generally are referred to as ''Part D sponsors'' in our rules. Section 1860D–12 of the Act contains the majority of provisions governing the contracts CMS enters into with the Part D sponsors. That section, entitled, ''Requirements for and contracts with prescription drug plan (PDP) sponsors,'' incorporates by reference many of the contract requirements that previously were applicable to Medicare+Choice (now Medicare Advantage) plans.

One of the incorporated provisions at section 1860D–12(b)(3)(D)of the Act is section 1857(e)(1) of the Act, which provides broad authority for the Secretary to add terms to its contracts with Part D sponsors, including terms that require the sponsor to provide the Secretary ''with such information * * * as the Secretary may find necessary and appropriate.'' We believe that the broad authority of section 1860D–12(b)(3)(D) of the Act authorizes us to collect much of the information CMS is already collecting in order to properly pay sponsors under the statute. However because, as discussed below, the statutory section governing CMS's payment of Part D sponsors (section 1860D–15 of the Act) contains provisions that might be viewed as limiting such collection, we are engaging in this rulemaking in order to resolve the statutory ambiguity, as well as to explain how we plan to implement the broad authority of section 1860D–12(b)(3)(D) of the Act.

Most of the payment provisions with respect to Part D sponsors are found in

section 1860D–15 of the Act.[1] Sections 1860D–15(d) and (f) of the Act authorize the Secretary to collect any information he needs to carry out that section; however, those subsections also state that ''information disclosed or obtained pursuant to [the provisions of section 1860D–15 of the Act] may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out [section 1860D–15 of the Act].'' (sections 1860D–15(d)(2)(B) and (f)(2) of the Act).

In the January 28, 2005 Medicare prescription drug benefit final rule (70 FR 4399), we stated that the section 1860D–15 of the Act restriction applies only in cases where section 1860D–15 of the Act is the authority for collecting the information. Where information is collected under an independent authority (even if the collected information duplicates the data collected under section 1860D–15 of the Act) no restriction would apply. Thus, for example, we noted that quality improvement organizations (QIOs) have independent authority to collect Part D claims data in order to evaluate the quality of services provided by Part D sponsors and would not be barred from collecting such data despite the restrictions of section 1860D–15 of the Act. In the January 28, 2005 final rule (70 FR 4399) we stated the following:

[W]e interpret sections 1860D–15(d) and (f) of the Act as limiting the use of information collected under the authority of that section. If information is collected under some other authority, however, we do not believe that section 1860D–15 of the Act would limit its use-because the information would not be collected ''pursuant to the provisions'' of section 1860D–15 of the Act. QIOs have independent authority to collect data, and to fulfill their responsibilities. To the extent QIOs need access to data from the transactions between pharmacies and Part D sponsors, these data could be extracted from the claims data submitted to us.

Similar to the statutory provisions authorizing QIOs to collect the information they need to perform their statutory duties, section 1860D–12(b)(3)(D) of the Act recognizes that the Secretary will need to collect a broad array of data in order to properly carry out his responsibilities as Secretary of the Department of Health and Human Services. Thus, if the Secretary determines it is necessary and appropriate for him to collect Part D data in order to carry out responsibilities outside section 1860D–15 of the Act, then section 1860D–15 of the Act would not serve as an impediment to such collections.

We also do not believe that language in sections 1860D–12(b)(3)(D) and 1857(e)(1) of the Act noting that the authority to collect information exists only ''except as otherwise provided,'' and in a manner that is ''not inconsistent with this Part,'' would serve as a hindrance to the independent collection of Part D claims. Again, this is due to the clear language of section 1860D–15 of the Act, which, on its face, restricts the use of information only when such information is collected under the authority of that section. Thus, nothing in section 1860D–15 of the Act will conflict with or be inconsistent with claims information collected under the authority of section 1860D–12(b)(3)(D) of the Act.

Most likely Congress included the broad grant of authority in section 1860D–15 of the Act in order to ensure that the Secretary—without engaging in any rulemaking—would have the legislative authority to collect any necessary data in order to pay Part D sponsors correctly. However, we do not believe that the Congress intended to restrict the Secretary when the Secretary otherwise has independent authority to collect identical information to that collected under section 1860D–15 of the Act. For example, the Secretary will need to evaluate Part D claims information in order to determine how access to Part D drug benefits affects beneficiary utilization of services under Parts A and B of the Medicare program. When Congress enacted the MMA, one of the stated reasons was to ensure that ''by lowering the cost of critical prescription drugs, seniors will better be able to manage their health care, and ultimately live longer, healthier lives.'' Press Release, House Ways and Means Committee, Seniors' Wait for Affordable Rx Drugs Comes to an End. President Bush Signs Historic Medicare Bill into Law (December 8, 2003) (available at *http://waysandmeans.house.gov/news.asp*). In order to determine whether lowering the costs of prescription drugs actually reduces health expenditures or improves health outcomes for seniors, however, the Secretary will need to match individual level Parts A and B data with Part D claims data. In this way, the Secretary will be able to evaluate the effectiveness and efficiency of the Part D benefit and report to Congress and others on the progress of the program.

Similarly, we do not believe that section 1860D–15 of the Act was intended to prohibit the Secretary from reporting to both the public and to the Congress. For example, we are required to report to the Congress regarding whether mandated disease management demonstrations are budget neutral and whether beneficiaries in these demonstrations are on the appropriate medications. Part D claims data are needed for these budget neutrality calculations as well as quality measures assessing appropriate use of medications. We may also need to make reports under the Part D program, for example, the publication of statistics detailing aggregate Medicare and beneficiary spending by class of drug, average number of drugs used by beneficiaries, total Medicare program spending, and other similar statistics. In order to derive such statistics, we would need to collect Part D claims data. These examples demonstrate that in a wide variety of situations it will be ''necessary and appropriate'' for CMS to evaluate the same information collected under section 1860D–15 of the Act, even though such information would not be used to implement section 1860D–15 of the Act. In these situations, we believe the clear language of section 1860D–12(b)(3)(D) of the Act provides the authority to collect the necessary information, and nothing about such collection will be inconsistent or in conflict with any other part of the statute.

II. Provisions of the Proposed Rule

A. Information To Be Collected

[If you choose to comment on issues in this section, please include the caption ''Information to be collected'' at the beginning of your comments.]

We would be collecting the same claims information collected under section 1860D–15 of the Act. We note that although section 1860D–12(b)(3)(D) of the Act would permit us to independently collect claims data from Part D sponsors, in order to ensure that Part D sponsors would not have to submit the claims information twice, we propose to access the claims data submitted under section 1860D–15 of the Act. This access avoids Part D sponsors engaging in duplicative efforts. Thus throughout this preamble, we may refer to ''accessing'' rather than ''collecting'' Part D data. The claims data for 2006 includes 37 data elements. We refer readers to the Prescription Drug Event data instructions which can be accessed at *http://www.cms.hhs.gov/DrugCoverageClaimsData/01_PDEGuidance.asp#TopOfPage* for a full description of this information. These instructions define each data element and its specific potential use for

[1] We note that there are other provisions outside of section 1860D–15 that also contain payment provisions. For example, section 1860D–14 discusses how CMS pays low-income subsidy.

CMS's payment process. Generally stated, these data elements include the following:

- Identification of the Part D sponsor and Part D plan through contract number and plan benefit package identification number.
- Health insurance claim number, which identifies the particular beneficiary receiving the prescription.
- Patient date of birth and gender.
- Date of service.
- Date paid by the plan.
- Identification of pharmacy where the prescription was filled.
- Identification of prescribing health care professional.
- Identification of dispensed product using national drug code (NDC) number.
- Indication of whether drug was compounded or mixed.
- Indication of prescriber's instruction regarding substitution of generic equivalents or order to ''dispense as written.''
- Quantity dispensed (for example, number of tablets, grams, milliliters, or other unit).
- Days supply.
- Fill number.
- Dispensing status and whether the full quantity is dispensed at one time, or the quantity is partially filled.
- Identification of coverage status, such as whether the product dispensed is covered under the plan benefit package or under Part D or both. This code also identifies whether the drug is being covered as part of a Part D supplemental benefit.
- Indication of whether unique pricing rules apply, for example because of an out-of-network or Medicare as Secondary Payer services.
- Indication of whether beneficiary has reached the catastrophic coverage threshold—which triggers reduced beneficiary cost-sharing and reinsurance payments.
- Ingredient cost of the product dispensed.
- Dispensing fee paid to pharmacy.
- Sales tax.
- Amount paid on the claim that is both below and above the catastrophic coverage threshold.
- Amount paid by patient and not reimbursed by a third party (such as copayments, coinsurance, or deductibles).
- Amount of third party payment that would count toward a beneficiary's ''out of pocket'' costs in meeting the catastrophic coverage threshold, such as payments on behalf of a beneficiary by a qualifying State Pharmacy Assistance Program (SPAP).
- Low income cost sharing subsidy amount (if any).
- Reduction in patient liability due to other payers paying on behalf of the beneficiary. This would exclude payers whose payments count toward a beneficiary's out of pocket costs, such as SPAPs.
- Amount paid by the plan for standard benefits, such as amounts paid for supplemental Part D benefits.

B. Purpose of CMS Collecting Information

[If you choose to comment on issues in this section, please include the caption ''Purpose of CMS Collecting Information'' at the beginning of your comments.]

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

- Reporting to the Congress and the public on the overall statistics associated with the operation of the Medicare prescription drug benefit;
- Conducting evaluations of the Medicare program;
- Making legislative proposals with respect to the programs we administer, including the Medicare, Medicaid, and the State Children's Health Insurance Program; and
- 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 § 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.[2] 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.

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:

- Ingredient cost of the product dispensed.
- Dispensing fee paid.
- Sales tax.
- Amount paid on the claim that is both below and above the catastrophic coverage threshold.
- Amount paid by a patient and not reimbursed by a third party.
- Amount of third party payment that would count toward a beneficiary's out-of-pocket costs in meeting the catastrophic threshold.
- Low income cost sharing subsidy amount, if any.
- Reduction in patient liability due to other payers paying on behalf of the beneficiary.
- Amount paid by the plan for standard benefits.
- Amount paid by the plan for nonstandard benefits.
- Identification of coverage status.
- Identification of dispensed product using the national drug code number.
- Identification of whether the drug was compounded or mixed.
- Identification of prescriber's instruction regarding substitution of generic equivalents or order to ''dispense as written''.
- Quantity dispensed.
- Days supply.
- Fill number.
- 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).
- 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 § 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® and Claritin®) 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

[2] 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.''

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 § 423.505(b)(8) by clarifying that Part D plan sponsors must comply with the disclosure and reporting requirements set forth by § 423.505(f). Furthermore, we propose to add a new § 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—

- Reporting to the Congress and the public or both on overall statistics associated with the operation of the Medicare prescription drug program;
- 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;
- Making legislative proposals to the Congress regarding Federal health care programs and related programs;
- Conducting demonstration projects and making recommendations for improving the economy, efficiency, or effectiveness of the Medicare program.

C. Sharing Data With Entities Outside of CMS (Proposed § 423.505(f)(5))

[If you choose to comment on issues in this section, please include the caption ''Sharing Data with Entities Outside of CMS'' at the beginning of your comments.]

In addition to collecting claims data for use in administering the Medicare Part D program under the authority of section 1860D–12(b)(3)(D) of the Act, CMS also believes that it is in the interest of public health to share some of the information collected under that authority with entities outside of CMS. As stated above, when information is collected under the authority of section 1860D–12(b)(3)(D) of the Act, we do not believe that the statutory language in section 1860D–15(d) and (f) of the Act (requiring the information collected under the authority of that section to be used only in implementing such section) would apply, since any initial collection would be effectuated outside of section 1860D–15 of the Act. Therefore, we are proposing to add § 423.505(f)(5) that would specify that we could use and share the claims information we collect under § 423.505(f) with both outside entities and other government agencies, without regard to any restriction included in § 423.322(b).

1. Other Government Agencies

In particular, Department of Health and Human Services' public health agencies such as NIH, FDA, and AHRQ have researchers that would also need to use Medicare Part D prescription drug related data for studies to improve public health consistent with the missions of these agencies. These studies will assess outcomes, and investigate clinical effectiveness, appropriateness of health care items and services (including prescription drugs), and develop strategies for improving the efficiency and effectiveness of clinical care. In addition, we believe that oversight agencies, such as the OIG, GAO, and CBO would need access to both aggregated and nonaggregated claims data in order to conduct evaluations of the Part D program. The NIH would need access to Medicare Part D data, linked to data from Medicare Parts A and B, in order to address its mission of conducting and supporting research regarding the cause, diagnosis, prevention, and cure of human diseases in order to improve the health of the nation. A wealth of information about diseases and their treatments can potentially be obtained from observational studies of therapeutic drug usage in Medicare patients. 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 and prevalence of particular diseases, disease progression, and the health outcomes of people with the diseases, trends in disease and their treatments, and even the relative effectiveness of alternative therapeutic approaches. Moreover, matching Part D claims data with the Surveillance Epidemiology and End Results (SEER) cancer registry would enable additional studies of cancer treatment and outcomes. Given the large number of patients involved, studies could also be designed to identify comorbidities that would be undetectable in conventional, prospective cohort studies. In addition, studies that correlate drug prescribing patterns with geography or patient demographics or examine trends over time could be used to identify differences and possible remediable problems with the health care system, to assess the magnitude of health disparities related to the delivery of care and indirectly assess the impact of new medical findings and other influences

on prescribing and other health care practices.

We also propose to share the information collected under the authority of section 1860D–12(b)(3)(D) of the Act with the FDA. The FDA's mission includes a mandate to ensure the safety and efficacy of drugs for the American people. Patients age 65 and older are more likely to experience serious or fatal adverse drug events than younger individuals because of their generally poorer health and because they typically take multiple medications for chronic conditions, which increases their opportunity for experiencing adverse drug effects. Part D data could be used to monitor patterns of drug use in the elderly and the disabled with the goal of identifying unsafe or suboptimal patterns of use, either with respect to the particular types of drugs being used or with respect to the dose or duration of use of these drug products. Additionally, Part D data could be used to identify rare but serious complications that certain patients may have with drugs more quickly and effectively than is achieved with the current surveillance systems. Formal epidemiologic studies could also be performed, to examine the nature and magnitude of risk conferred by particular medications, to identify risk factors for adverse event occurrence, or to assess the effect of risk management programs intended to reduce prescription drug risks.

A third agency we believe would need access to the Part D claims data is the Agency for Healthcare Research and Quality (AHRQ). AHRQ's mission to conduct health services and outcomes studies in assessing the effectiveness of health care items and services, improving the quality of health care, promoting efficiency and patient safety, and reducing medical error will be enhanced by access to Medicare Part D claims data. Section 1013 of the MMA requires AHRQ to conduct research, demonstrations, and evaluations designed to improve the quality, effectiveness, and efficiency of Medicare, Medicaid, and the State Children's Health Insurance Program. To implement section 1013 of MMA, AHRQ has established a new research initiative called the Effective Health Care (EHC) program. The EHC program supports research on the outcomes, comparative clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services. Included in the EHC program is a research network of 13 centers with over 60 affiliated health scientists and the capacity to—(1) scientifically analyze administrative, survey, and clinical databases; (2) develop and apply new scientific methods, instruments, and methodologies; and (3) operate and analyze computerized surveillance and monitoring systems. The availability of Medicare Part D data, linked to data from Medicare Parts A and B, would greatly enhance the capacity of the EHC program to carry out research and program evaluations designed to improve the quality of CMS programs as mandated in section 1013 of the MMA.

Other agencies within DHHS, such as the Centers for Disease Control and Prevention, the Health Resources and Services Administration (HRSA), or the Office of the Assistant Secretary for Planning and Evaluation, may also need the prescription drug data to perform evaluations or assess policies.

We believe oversight agencies may also require access to the Part D claims data. These agencies would include the Office of the Inspector General (OIG), the Government Accountability Office (GAO), the Congressional Budget Office (CBO), and the Medicare Payment Advisory Commission (MedPAC). We believe these agencies may require access to data in order to evaluate the cost-effectiveness of various policies under the Part D program, to evaluate spending for various classes of drugs under such program, to analyze brand-name versus generic prescribing trends, and to conduct other oversight activities that are not specifically related to payment. For these reasons, we believe it would be appropriate to share some Part D data with these oversight agencies.

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

2. External Researchers

External researchers, such as those based in universities, regularly request and analyze Medicare data for their research studies, many of which are designed to address questions of clinical importance. We believe researchers who study a broad range of topics need access to the Part D claims linked to Parts A and B claims data as well. The research questions that have been previously addressed through analyses of Parts A and B claims have contributed to very significant improvements in the public health, have been critical in assessing the quality of care and costs of care for patients in the Medicare program, and have in many cases spurred other types of research. As such, we believe that a data source that includes Parts A and B claims as well as their attendant Part D claims would be used in a similarly constructive manner, such that greater knowledge on a range of topics, both clinical and economic, will be generated. This knowledge is expected to contribute positively to the evaluation and functioning of the Medicare program, and to improve the clinical care of beneficiaries.

We will specifically address the needs of a segment of external researchers as part of our implementation of section 723 of the MMA, which requires the Secretary to develop a plan to ''improve the quality of care and reduce the cost of care for chronically ill Medicare beneficiaries.'' Congress specifically stated that the plan should provide for the collection of data in a data warehouse (*see* section 723(b)(3) of the MMA). We will implement section 723 of the MMA by populating a chronic care condition data warehouse (CCW) which would be accessible by private researchers in order for such researchers to conduct studies related to improving quality and reducing costs of care for chronically ill Medicare beneficiaries. The CCW will include a beneficiary sample and will include Part D claims, in order to allow researchers to analyze prescription drug information. In this way, 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.

In addition to the section 723 of the MMA data warehouse, we are planning to make available Medicare Part D claims data linked to other Medicare claims files to external researchers on the same terms as other Medicare Parts A and B data are released today, with appropriate protections for beneficiary confidentiality. These data would be disseminated under our standard data use agreement protocols. This means that each data request would be evaluated to determine whether—

- A legitimate research purpose is presented by a responsible party,
- The minimum data needed to conduct the study will be released, and
- The confidentiality of beneficiary information is protected.

See our Agreement for Use of Centers for Medicare and Medicaid Services Data Containing Individual Specific Information at *http://www.resdac.umn.edu/docs/CMS-R-02352-v2-locked.doc*. In addition, we would ensure that our system of records for claims data would permit these usages of the data.

We request comments on the proposed use of the data for research purposes that would help CMS in its efforts to improve knowledge relevant to public health. We also ask for comments on whether we should consider additional regulatory limitations for external researchers beyond our existing data use agreement protocols in order to further guard against the potential misuse of data for non-research purposes, commercial purposes, or to ensure that proprietary plan data or confidential beneficiary data is not released.

D. Beneficiary Access to Part D Data

[If you choose to comment on issues in this section, please include the caption ''Beneficiary Access to Part D Data'' at the beginning of your comments.]

We are considering the use of Part D claims data for projects involving the development of personalized beneficiary medication history record that would be accessible by Medicare beneficiaries. We are requesting comments on this proposed use of Part D data collected under the authority of section 1860D–12(b)(3)(D) of the Act.

E. Applicability

[If you choose to comment on issues in this section, please include the caption ''Applicability'' at the beginning of your comments.]

The proposed revision does not affect the applicability of HIPAA to the Department or any other appropriate parties, nor does it affect the applicability of the Privacy Act (5 U.S.C. 552a and b) or the Trade Secrets Act (18 U.S.C. 1905).

F. Limitations

[If you choose to comment on issues in this section, please include the caption ''Limitations'' at the beginning of your comments.]

This proposed rule in no way affects or limits our already existing ability to collect data that is not identical to that collected under section 1860D–15 of the Act, such as enrollment, formulary, price comparison, quality assurance and utilization review data. Much of that data is already collected under other authorities in the statute. For example, section 1860D–1(c)(1) of the Act allows for data collection, such as price comparison data, to facilitate providing information to beneficiaries in order to allow informed decisions among the available choices for Part D coverage (*see* also § 423.48). Similarly, section 1860D–4(c) of the Act authorizes data collection to evaluate sponsors' utilization management, quality assurance, medication therapy management, and fraud, waste and abuse programs (*see* § 423.153(b)(3), (c)(5), and (d)(6)). Even in cases where data collection is not specifically mandated by statute, to the extent the collection is not identical to the data collected under section 1860D–15 of the Act, we do not believe it is necessary to resolve any statutory ambiguity, because the section 1860D–15 of the Act rules on using such information would not apply. Finally, this proposed rule does not address uses already permitted under section 1860D–15 of the Act, such as OIG or others conducting audits and evaluations necessary to ensure accurate and correct payment and to otherwise oversee Medicare reimbursement under Part D, price variation studies, risk score refinement studies including the mandated geographic variation in price and utilization study, the reinsurance demonstration evaluation, or other such uses.

III. Collection of Information Requirements

This document does not impose new information collection requirements on Medicare Part D plans. Medicare Part D sponsors are already required to submit Medicare Part D claims information by virtue of section 1860D–15 of the Act.

Consequently, since there are no new information collection requirements on Medicare Part D plans, this document will not require a review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). Neither plan sponsors nor pharmacies are required to perform any new task or purchase any new equipment or increase their labor force. This proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined that this rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. This proposed rule impacts Part D sponsors, not small rural hospitals.

Therefore we are not preparing an analysis for section 1102(b) of the Act, because we have determined that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This proposed rule will have no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this regulation does not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 423

Administrative practice and procedure, Medicare, Prescription Drugs, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV part 423 as follows:

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

1. The authority citation for part 423 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152 and 1395hh).

Subpart K—Application Procedures and Contracts with PDP Sponsors

2. Section 423.505 is amended by—

A. Revising paragraph (b)(8).

B. Redesignating paragraph (f)(3) as (f)(4).

C. Adding new paragraphs (f)(3) and (f)(5).

The revision and additions read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(8) Comply with the disclosure and reporting requirements in § 423.505(f), § 423.514, and § 423.329(b) for submitting current and prior drug claims and related information to CMS for its use in risk adjustment calculations and for the purposes of implementing § 423.505(f), § 423.514, and § 423.329(b).

* * * * *

(f) * * *

(3) Drug claims and related information, as the Secretary deems necessary and appropriate for purposes including but not limited to—

(i) Reporting to Congress and the public on overall statistics associated with the operation of the Medicare prescription drug program;

(ii) Conducting evaluations of the overall Medicare program, including the interaction between prescription drug coverage under Part D of Title XVIII of the Social Security Act and the services and utilization under Parts A, B, and C of title XVIII of the Act and titles XIX and XXI of the Act;

(iii) Making legislative proposals to the Congress regarding Federal health care programs and related programs; and

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

* * * * *

(5) CMS may use the information collected under this subsection and share it with other government agencies and outside entities, in accordance with applicable Federal law. Any restriction set forth by § 423.322(b) must not be construed to limit the Secretary's authority for these purposes.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: July 11, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 21, 2006.

Michael O. Leavitt,

Secretary.

Editorial Note: The following Appendix will not appear in the Code of Federal Regulations.

Appendix A—Current CMS Studies

1. Effect of Part B vs. Part D Drug Coverage

On January 1, 2005, the Secretary reported to Congress on his recommendations for providing benefits under Part D for outpatient prescription drugs which are currently covered under Part B. The report was mandated in section 101(c) of the MMA. The study concluded that, while it would not be desirable to move coverage of separately billable Part B drugs to Part D for most categories of Part B drugs, it may be worth considering for a limited number of drugs. The report recommended that the decision with respect to changing coverage for this limited number of drugs be based upon experience with the Medicare Replacement Drug Demonstration (which provided Medicare coverage for certain drugs between enactment of MMA in 2003 and the start of the Part D drug benefit in 2006) and at least 2 years of experience with the Part D program.

This follow-on study would further examine the relationship between Part B and Part D drug coverage using Part B and Part D claims and would include an assessment of the impact of such a change on beneficiaries, Part D sponsors and the Federal budget.

2. Dual Eligible Drug Coverage Transition From Medicaid to Medicare

We will analyze Part D claims and other data for changes in dual eligibles' drug use and costs and the impact of the change in drug coverage on other Medicare and Medicaid services. Baseline drug data from Medicaid will allow person-level studies that analyze pharmacy use linked to all other Medicare (Parts A, B, and D claims) and Medicaid benefits before and after MMA implementation. The study will examine Medicare and Medicaid interactions with pharmacy services for specific subpopulations including people with disabilities and chronic diseases in community or institutional settings.

3. Evaluation of Disease Management Interventions

CMS has several projects underway to evaluate the impact of Congressionally mandated disease management interventions (for example, sections 649 and 721 of the MMA, and earlier legislation) on beneficiary health outcomes, satisfaction, and Medicare expenditures. Part D claims data will be used to estimate the effects of these programs on adherence to evidence based medicine, such as the percent of patients who are on the appropriate medications for their condition. Part D claims data will be used to measure the cost/utilization differences between control and intervention groups in these programs, and to assess the costs of their medications. A very important aspect of disease management interventions is to reduce adverse drug interactions. Access to Part D claims data would allow us to assess whether the disease management intervention has any impact on polypharmacy.[3] All of these are factors which disease management programs are expected to influence. Part D data claims data

[3] ''Polypharmacy'' is defined most simply as ''excessive or unnecessary use of prescription or nonprescription medications.'' From Critical Thinking: Administering Medications to Elderly Patients (2007) citing Jones, 1997.

will also be used in budget neutrality calculations.

4. Medicare Health Care Quality Demonstration

Section 646 of the MMA mandates a 5-year demonstration program under which we will test major changes to improve quality of care while increasing efficiency across an entire health care system. Broadly stated, the goals of the Medicare Health Care Quality demonstration are to improve patient safety; enhance quality; increase efficiency; and reduce scientific uncertainty and the unwarranted variation in medical practice that results in both lower quality and higher costs. Projects approved under this demonstration will be expected to achieve significant improvements in safety, effectiveness, efficiency, patient-centeredness, timeliness and equity: the six aims for improvement in quality identified by the Institute of Medicine in its Crossing the Quality Chasm report.

Each factor to be addressed in the evaluation of this demonstration can be directly or indirectly related to prescription drug use, hence the need for Part D claims and other data. For example, research on patient safety has illuminated the way that prescription drug errors represent a nexus that ties together the benefits of health information technology and the need to reduce care fragmentation, and improve care coordination.

5. Expanded Coverage for Chiropractic Services Evaluation

Section 651 of the MMA mandated a budget neutral chiropractor demonstration. Achievement of budget neutrality for the expanded coverage of chiropractic services under the demonstration is likely to depend on the abilities of these services to substitute for the use of ambulatory services by allopathic physicians (for example, primary care physicians, orthopedic surgeons, and, possibly, neurologists) and to reduce the need for medications. Prevention of the need for surgical procedures and associated hospitalizations is also possible, but is likely to be infrequent over the course of a 2-year demonstration.

Information on medication consumption under Part D will be a key component of the evaluation. For example, use of pain medications may be reduced by chiropractic services in patients with back pain, extremity pain due to arthritis, and in patients with migraine headaches. Reduction in the use of pain medications may, in turn, have beneficial effects on the need for treatment of complications associated with these medications.

6. Adult Medical Day Care Evaluation

Section 703 of the MMA mandated an adult medical day care demonstration. In the evaluation, we will compare patient outcomes and costs of furnishing care for beneficiaries receiving some of their home health services in an adult day care setting, with outcomes and costs for beneficiaries receiving these services principally at home under current rules. Drug claims will be used to help identify matched comparison groups and to explore differences between beneficiaries who elect to enroll in the demonstration and those who decline to enroll or are excluded.

7. Follow-Up of Medicare Beneficiaries Enrolled in the Medicare Replacement Drug Demonstration

Section 641 of the MMA mandated the Medicare Replacement Drug Demonstration that served as a bridge to the implementation of a full-scale Medicare prescription drug benefit. It targeted vulnerable beneficiaries with disabling or life threatening conditions. Many of the covered drugs were expensive ''specialty'' biologics, costing more than $20,000 per year. A review of benefit designs under Part D suggests specialty drugs are commonly being placed on fourth and fifth tiers with relatively high levels of patient cost sharing. Plan-level information from Part D coupled with individual drug claims data will allow us to examine levels of plan uptake among demonstration participants, the features of plan design selected, and the effect of Part D on patient cost-sharing for this vulnerable population.

8. Value-Based Purchasing Initiatives

Many evidence-based guidelines underscore the importance of pharmacologic therapy to providing high-quality patient care. Yet, under prescribing of drugs with a known beneficial effect remains a common problem (for example, beta-blockers for treatment of hypertensive patients with a history of myocardial infarction). As Medicare moves toward value-based purchasing, it will be critical to design a payment system that provides incentives for physicians to appropriately prescribe proven pharmacologic therapies. This will require individual Part D claims linkable to a physician's practice.

9. Medicare Physician Group Practice Demonstration

Section 412 of the Benefits Improvement and Protection Act mandated the Medicare Physician Group Practice Demonstration. This demonstration is a shared savings model that rewards physician groups for improving the quality and efficiency of health care services delivered to Medicare FFS beneficiaries. The financial model includes all Part A and Part B spending for beneficiaries assigned to the physician group as well as for the comparison population. Part D claims data will be used for budget neutrality calculations. Physician groups can also use the Part D claims data to improve quality by managing medications for their Medicare patients.

10. Chronic Care Data Warehouse

Section 723 of the MMA mandates development of recommendations for improving the quality of care for chronically ill Medicare beneficiaries. To implement this sector we are developing a chronic care warehouse to be made available to researchers who want to study chronic illnesses in the Medicare population. The CCW consolidates beneficiary level Medicare enrollment and utilization data with MDS and OASIS assessment data to facilitate the study of the Medicare population with chronic conditions. Congress specifically directed us to identify any new data needs and develop a methodology to address these data needs. The absence of drug data is a significant gap in data available to study chronically ill Medicare beneficiaries. Integrating Part D enrollment information and drug claims data into the CCW will address this data need and greatly enhance the analytic power and utility of the CCW.

[FR Doc. 06–8750 Filed 10–13–06; 4:05 pm]

BILLING CODE 4120–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 06–1901; MB Docket No. 06–11; RM–11304]

Radio Broadcasting Services; Crowell, TX

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; dismissal.

SUMMARY: At the petitioner's request, the Audio Division has dismissed the proposal of Jeraldine Anderson (''Anderson'') to allot Channel 250A at Crowell, Texas. Anderson had filed a petition for rule making proposing the allotment of Channel 250A at Crowell, Texas, as the community's second local FM transmission service. The Audio Division further dismissed the counterproposal submitted in the proceeding by Linda Crawford (''Crawford''), upon Crawford's request to withdraw that proposal. Finally, the Audio Division dismissed the counterproposal submitted in the proceeding by LKCM Radio Group, L.P., licensee of FM Station KFWR, Mineral Wells, Texas; Fort Worth Media Group GP, LLC, licensee of FM Station KYBE, Frederick, Oklahoma; and LKCM Radio Licenses, LP, the proposed assignee of KFWR and KYBE (collectively, ''Joint Parties''). The Joint Parties' counterproposal was dismissed for failure to meet the Commission's minimum distance separation requirements with respect to FM Station KRZB, Channel 248C2, Archer City, Texas.

FOR FURTHER INFORMATION CONTACT: Deborah Dupont, Media Bureau, (202) 418–2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 06–11, RM–11304, adopted September 20, 2006, and released September 22, 2006. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Information Center,