

## **Supporting Statement For Collection Requirements pertaining to the Medicare Prescription Drug Benefit Program**

### **A. Background**

The Centers for Medicare and Medicaid Services (CMS) published a proposed rule to establish the Medicare Prescription Drug Benefit on August 3, 2004. The proposed rule identified options and alternatives to the provisions we proposed and we strongly encouraged comments and ideas on our approach and on alternatives to help us design the Medicare Prescription Drug Benefit Program to operate as effectively and efficiently as possible in meeting the needs of Medicare beneficiaries.

The final rule revising these sections was published on January 28, 2005. The PRA requirements referenced in this PRA submission, as reflected in the final regulation, assisted in the implementation of the provisions of the Social Security Act (the Act) establishing and regulating the Medicare Prescription Drug Benefit. The new voluntary prescription drug benefit program was enacted into law on December 8, 2003 in section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). The MMA specifies that the prescription drug benefit program will become available to beneficiaries beginning on January 1, 2006.

Generally, coverage for the prescription drug benefit will be provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which will offer prescription drug coverage that is integrated with the health care coverage they provide to Medicare beneficiaries under Part C of Medicare. PDPs must offer a basic prescription drug benefit. MA-PDs must offer either a basic benefit or broader coverage for no additional cost. If this required level of coverage is offered, MA-PD's or PDP's but not fallback PDP's may also offer supplemental benefits through enhanced alternative coverage for an additional premium. All organizations offering drug plans will have flexibility in the design of the prescription drug benefit. Consistent with the MMA, these requirements also provide for subsidy payments to sponsors of qualified retiree prescription drug plans.

The submission seeks OMB re-approval of the regulatory requirements associated with section 101 of Title I of the MMA (Pub. L. 108-173). Separate OMB approval was sought for each form or instruction subsequently developed from these regulatory PRA requirements, as required.

We have also concluded that any changes to these regulations as proposed under our current draft rule (CMS 4131-P) will not impact small businesses nor require additional paperwork burden on Part D sponsors. We anticipate CMS 4131-P will be published in April 2008.

### **B. Justification**

## 1. **Need and Legal Basis**

These information collection requirements are mandated by 42 CFR Part 423—Voluntary Medicare Prescription Drug Benefit. Note that the regulations—

- for Medicare supplemental policies (Medigap) will continue to be located in 42 CFR part 403 (subpart B);
- for exclusions from Medicare and limitations on Medicare payment (the physician self-referral rules) will continue to be located in 42 CFR part 411;
- for managed care organizations that contract with us under cost contracts will continue to be located in 42 CFR part 417, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans;
- for PACE organizations will continue to be located in 42 CFR part 460.

Section 101 of Title I of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) added sections 1860D-1 through D-42 and sections Sec. 102, Sec. 103, Sec. 104 and Sec. 109 to the Social Security Act (the Act) establishing to establish this new program.

## 2. **Information Users**

Part D plans use the information discussed below to comply with the eligibility and associated the Part D participating requirements. CMS will use this information to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and to ensure that correct information is disclosed to enrollees, both potential enrollees and enrollees.

## 3. **Improved Information Technology**

Where feasible the collection of information covered by this regulation will involve the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy.

## 4. **Duplication of Similar Information**

The information collection requirements contained in the regulations are not duplicated through any other effort.

## 5. **Small Businesses**

Some Part D Organizations are small businesses so they may be affected. They will have to comply with all the information requirements described in this supporting statement.

## 6. **Less Frequent Collection**

This information is collected as needed. If it were to be collected less frequently, CMS would not be able to obtain this data. Some of the consequences would be improper or erroneous payment to Part D plans, improper enrollment of beneficiaries in an organization, the release of misleading information regarding health care coverage through a plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. **Special Circumstances**

Generally, information collections contained in the Part D drug program occur annually or quarterly. Special circumstances may require information to be submitted to the agency more often than quarterly. (See section 12 below for specific instances.)

8. **Federal Register Notice/Outside Consultation**

The required Federal Register notices were published on August 3, 2004 (69 FR 46632) and in January 2005 to announce the new or revised information collection requirements. The public meetings were held in February at CMS and written comments were received which were in turn utilized by CMS during the regulations drafting stage. Also, as necessary CMS consulted with technical experts and industry and beneficiary advocates as necessary to obtain their opinions on provisions of the statute; two examples were on long term care policy and Coordination of benefits and TrOOP facilitation. In developing our long term care policy, we consulted with the Lewin Group for technical expertise on the industry; we also engaged industry and beneficiary representatives on the impacts that a Plan delivered long term care benefit would have on each constituency. In developing our solutions for coordinating benefits and facilitating TrOOP calculation, we consulted extensively with industry representatives from pharmacies, PBMs, Plans, switches and other groups. These consultations continued as we implement the final rule.

No further outside consultations were necessary for this revised information collection since the program has taken effect on January 1, 2006. Therefore, the revisions to the collection is based on program experience.

9. **Payments/Gifts To Respondents**

There are no payments/gifts to respondents.

10. **Confidentiality**

The collection of information from the applicants and contracting organizations that pertain to their financial records and submission of data to comply with the proposals have been determined by CMS's Freedom of Information officer to be proprietary and confidential. The information collected from organizations for the purposes of disclosing to the potential enrollees their health care coverage choices is public information and in fact is being

collected for purposes of the National Medicare Education Program, whose purpose is to broadly disseminate to the public objective, comparative information on benefits, program rules, and premiums of the contracting with organizations. The information collected from Medicare beneficiaries and contained in medical records and other health and enrollment information must conform to all requirements at 42 CFR Part 423 including all Federal and State laws regarding confidentiality and disclosure.

## 11. **Sensitive Questions**

There are no sensitive questions included in this collection effort.

## 12. **Burden Estimate (Total Hours & Wages)**

### **Subpart A--General Provisions**

Subpart A does not contain any requirements subject to the PRA.

### **Subpart B--Eligibility and Enrollment.**

#### **§ 423.32 Enrollment process.**

(a) A Part D eligible who wishes to enroll in a Part D plan may enroll during the enrollment periods specified in §423.38, by filing the appropriate enrollment form with the Part D plan or through other mechanisms CMS determines are appropriate.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required enrollment application to a Part D plan sponsor. We estimate that it will take 30 minutes to complete and submit the required application to the Part D plan. During the first Part D initial enrollment period, it is estimated that 24 million individuals will complete and submit these applications. This estimate is based on preliminary estimates of the number of individuals who will enroll in Part D Plans in 2006. In 2007, and beyond, the number of enrollments will be substantially less, since an individual will generally be limited to changing Part D plans during the annual coordinated election period. Therefore, it is estimated 6 million individuals may change their Part D plans annually and that 2 million new beneficiaries will be making first time enrollments into Part D plans.

(b) Enrollment form or CMS-approved mechanism. The enrollment must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the Part D plans sponsor. Persons who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary.

The burden associated with this requirement is reflected above under section 423.32(a).

A Part D plans sponsor may require Part D eligible individuals enrolling or enrolled in its Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, in a form and manner approved by CMS.

The burden associated with the requirement for individuals to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other

third-party payment arrangement enrolled or enrolling in a Part D plan is total annual burden of 43,333 hours. We estimate that 2.6 million beneficiaries will need 1 minute to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of 43,333 hours.

(d) Notice requirement. The Part D plan sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of acceptance or denial of the individual's enrollment request. We estimate that during the first Part D initial enrollment period a total of 24 million notices will be disclosed, affecting approximately 64 Part D plans (based upon an estimate of 2 Part D plans per 34 regions). Given that each Part D plans will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan approximately 8 hours to produce each notice – either an acceptance or a denial notice must be provided. We further estimate that on average, it will take each Part D plan sponsor 1 minute to assemble and disseminate each notice. We further estimate that on average, it will take each sponsor 5,860 hours to disclose 375,000 notices during this first year. In 2007, and beyond, we estimate that 93,750 notices will be disclosed annually at 1,465 hours per sponsor. This assumption is based on the premise that once the notices have been standardized, a Part D plan sponsor will mass-produce and mail the required notices.

**§423.34 Enrollment of full-benefit dual eligible individuals.** Section 423.34(g)(2) states that the organization that receives the enrollment must provide notification that describes the costs and benefits of the new plan and the process for accessing care under the plan and their ability to decline the enrollment or choose another plan. Such notification must be provided to all potential enrollees prior to the enrollment effective date, in a form and manner determined by CMS.

The burden associated with this requirement is the time and effort put forth by the organization to provide such notification. We estimate it would take one organization 207 hours to comply with this requirement. We estimate 42 organizations would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 8700 hours.

**§423.36 Disenrollment process.**

(b) The Part D plan sponsor must submit a disenrollment notice to CMS within timeframes CMS specifies; provide the enrollee with a notice of disenrollment as CMS determines and approves; and file and retain disenrollment requests for the period specified in CMS instructions.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to an individual notice of disenrollment. We estimate that on an annual basis it will require a total of 576,100 notices, affecting each Part D plan sponsors to some degree, as described below. Given that each Part D plan sponsor will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that it will take each Part D plan sponsor approximately 8 hours to produce the standardized notice. We further estimate that on average, it will take each Part D plan 1 minute to disclose each notice.

§ 423.38 Enrollment periods.

(b) Under the Special Enrollment Period provisions, an individual is eligible to enroll in a Part D plan or disenroll from a Part D plan and enroll in another Part D plan, if the individual demonstrates to CMS, in accordance with guidelines CMS issues, that the Part D plan sponsor offering the Part D plan substantially violated a material provision of its contract under this part that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a Part D plan substantially violated a material provision of its contract. Based on our experience with the current Medicare Advantage program, we would expect that few, if any, individuals will avail themselves of this option. Generally, in those instances where CMS has found that an M+C organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

---

**§423.44 Involuntary disenrollment by the Part D plan.**

If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2) of this section (that is, other than death Part D eligibility), the Part D plan sponsor must give the individual timely notice of the disenrollment with an explanation of why the Part D plan is planning to disenroll the individual. Notices for reasons specified in paragraphs (b)(1) through (b)(2) of this section must be provided to the individual before submission of the disenrollment notice to CMS; and include an explanation of the individual's right to a hearing under the Part D plan's grievance procedures.

A Part D plan sponsor may disenroll an individual from the Part D plan for failure to pay any monthly premium if the Part D plan sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to submit the required materials to CMS demonstrating that the Part D plan sponsor made reasonable efforts to collect the unpaid premium amount and the time and effort necessary for a Part D plan sponsor to disclose to an individual the notice of disenrollment. We estimate that it will take a Part D plan 5 minutes to submit the required transaction to CMS for each occurrence and that each of the Part D plan sponsors will be required to submit the necessary documentation to CMS 960 times on an annual basis. We estimate that on an annual basis 96,000 individuals will be disenrolled for failure to pay premiums, and it will take each Part D plan 1 minute to disclose each notice and that each Part D plan will be required to disclose 960 notices on an annual basis for a annual burden of 16 hours.

A Part D plan may disenroll an individual whose behavior is disruptive, only after it meets the requirements described in this section and after CMS has reviewed and approved the request.

To disenroll an individual from its Part D plan, based on an individual's behavior, the Part D plan sponsor must document the enrollee's behavior, its own efforts to resolve any problems and any extenuating circumstances. The Part D plan must submit this information and any documentation received by the beneficiary to CMS. The Part D plan sponsor may request from CMS the ability to decline future enrollment by the individual.

The burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in this

section. We estimate that it will take a Part D plan 3 hours to capture and retain the required documentation for each occurrence and that each Part D plan will have 1 occurrence on an annual basis.

In addition, the Part D plan must inform the individual of the right to use the Part D plan's grievance procedures.

The burden associated with this requirement is captured under section § 423.128.

When a Part D plan contract terminates as stipulated under 423.507 and 423.510 the Part D plan sponsor must send a notice to the enrollee before the effective date of the plan termination or area reduction. The notice must give provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D.

The burden associated with these requirements is discussed below under sections 423.507 and 423.510.

#### **§ 423.46 Late enrollment penalty.**

Section 423.46(b) states that Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to obtain the required information. To comply with this requirement, Part D sponsors would expend 15 minutes per new Part D enrollee. We estimate that there will be approximately 500,000 new Part D enrollees. Therefore the total annual burden associated with this requirement will be 125,000 hours/ 7,500,000 minutes for all enrollees.

Section 423.46(d) requires the Part D plan sponsor to retain all information collected concerning a credible coverage period determination in accordance with the enrollment records retention requirements described in subpart K, §423.505(e)(1)(iii).

The burden associated with this requirement is the time and effort put forth by the Part D plan sponsor to retain the required information. To comply with this requirement, Part D sponsors would expend 5 minutes per new Part D enrollee. There are approximately 500,000 enrollees. We estimate the total annual burden associated with this requirement will be 41,667 hours/2,500,000 minutes for all new Part D enrollees.

#### **§ 423.48 Information about Part D.**

Each Part D sponsorplan and MA-PD organizationmust provide, on an annual basis, and in a format and using standard terminology that CMS may specify in guidance, the information necessary to enable CMS to provide to current and potential Part D eligible individuals the information they need to make informed decisions among the available choices for Part D coverage.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to submit the required materials to CMS. We estimate that on an annual basis it will take 87 Part D sponsors 2 hours to submit the required documentation to CMS for a total annual burden of 174 hours per sponsor. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents.

The estimated annual cost is \$4,569.24. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (174).

**§ 423.50 Approval of marketing materials and enrollment forms.**

(a) At least 45 days (or 10 days if using marketing materials that use, without modification, proposed model language as specified by CMS) before the date of distribution, the Part D plan sponsor must submit the its marketing materials and forms to CMS for review.

The burden associated with this requirement is the time and effort necessary for a Part D plan to submit the required materials to CMS. We estimate that on an annual basis it will take 87 Part D plan sponsors 2 hours to submit the required documentation to CMS for a total annual burden of 174 hours per sponsor. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents.

The estimated annual cost is \$4,569.24. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (174).

**§ 423.56 Procedures to document creditable status of prescription drug coverage.**

(b) Each entity that offers prescription drug coverage under any of the types described in § 423.56(b) must disclose, to all Part D eligible individuals whether such coverage meets the actuarial requirements specified in guidelines provided by CMS. These notices must be provided to Part D eligible individuals, at minimum, at the following times: (1) prior to an individual's initial enrollment period for Part D, as described under §423.38(a); (2) prior to the effective date of enrollment in the coverage, and upon any change in creditable status; (3) prior to the commencement of the Annual Coordinated Election Period (ACEP) which begins on November 15 of each year, as defined in 423.38(b); or (4) upon request by the individual. In an effort to reduce the burden associated with providing these notices, we revised our final regulations to allow most entities to provide notices of creditable and non-creditable status with other information materials that these entities distribute to beneficiaries (rather than separately) and, as discussed in the preamble, in September 2005 we provided model disclosure notices, CMS Form 10182, which provided model language for both types of notices.

The burden associated with this requirement is the time and effort necessary for each of these entities to disclose to an individual notice of coverage. The burden for the individual disclosure notices is accounted for under PRA package CMS -0938-0990. If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment fee described in §423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. While we have no way of determining how many individuals will apply to CMS, for the purpose of providing an upper bound estimate for public comment we estimate that on an annual basis it will take 100,000 individuals 15 minutes to apply to CMS, for a total of 25,000 hours.

(c) Each entity must disclose their creditable coverage status to CMS in the form and manner described by CMS. In January 2006, CMS issued guidance on the form and manner of the disclosure to CMS. Each entity was required to disclose their initial creditable coverage status to CMS in 2006, and within 60 days of the beginning date of their plan year, as well as upon any subsequent change in creditable coverage status. CMS provided an on-line Disclosure to CMS Form – CMS-10198 to satisfy this requirement.

The burden associated with this requirement is the time and effort necessary for each entity



to submit the required Disclosure to CMS Form. The burden for the individual disclosure notices is accounted for under PRA package CMS -0938-1013..

### **Subpart C--Benefits and Beneficiary Protections.**

#### **§ 423.104 Requirements related to qualified prescription drug coverage.**

(g) A Part D plan sponsor is required to disclose to CMS data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers, as well as data on aggregate negotiated price concessions obtained from pharmaceutical manufacturers that are passed through to beneficiaries, via pharmacies and other dispensers, in the form of lower subsidies, prices, and/or monthly beneficiary prescription drug premiums, in the manner and frequency specified by CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to CMS the aggregate negotiated price data on concessions. We estimate that on an annual basis it will take 142 PDP sponsors and PACE organizations and 606 MA organizations 10 hours to submit the required documentation to CMS for total annual burden of 7,480 hours. The estimated annual cost is \$196,424.80. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (7480).

#### **§ 423.120 Access to covered Part D drugs.**

(b) A Part D plan sponsor's formulary must be reviewed by a pharmacy and therapeutic committee that must maintain written documentation of its decisions regarding formulary development and revision.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor's pharmacy and therapeutic committee to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take 142 PDP sponsors and PACE organizations and 606 MA organizations 1 hour each to capture and retain the required documentation on an annual basis for total annual burden of 1496 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents. The estimated annual cost is \$39284.96. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (1496).

Prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D plan sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in §423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to provide notice of at least 60 days to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity will be creating disclosure notices for mass mailings, we are proposing the following burden estimates. We estimate that on an annual basis it will take each entity approximately 1 hour to produce the standardized notice. We estimate that on an annual

basis it will take each entity approximately 1 hour to produce the standardized notice. We further estimate that on average, it will take 142 Part D sponsors and 606 MA organizations 40 hours to disclose the required notice for a total annual burden of 29,920 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents.

The estimated annual cost is \$785,699.20. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (29920).

(c) A Part D sponsor must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

The burden associated with this requirement is the time and effort necessary for an entity to provide each enrollee a card. The burden associated with this requirement is reflected in section 423.128.

#### **§ 423.128 Dissemination of plan information.**

**(a) A part D sponsor must disclose information about its Part D plan(s) as required by this section to each enrollee of a Part D plan offered by the Part D sponsor under this part and to Part D eligible individuals.**

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to disclose information and materials about its Part D plan(s). We estimate that it will require 87 PDP sponsors and 606 MA organizations 80 hours on an annual basis to prepare the plan materials. We further estimate that on an annual basis, on average, it will require each entity 120 hours on an annual basis to disclose the required materials to enrollees and eligible individuals for a total annual burden of 138,600 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents. The estimated annual cost is \$3,639,636. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (138,600).

(e) A Part D sponsor must furnish directly to enrollees an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for 87 PDP sponsors and 606 MA organizations to provide an explanation of benefits when prescription drug benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials for total annual burden of 110,880 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents. The estimated annual cost is \$2,911,708.80. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (110,880).

#### **§ 423.132 Public disclosure of pharmaceutical prices for equivalent drugs.**

(a) Except as provided under paragraph (c) of this section, a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy.

Subject to paragraph (d) of this section, the information under paragraph (a) of this section must be provided after the drug is dispensed at the point of sale or, in the case of dispensing by mail order, at the time of delivery of the drug.

The burden associated with this requirement is the time and effort necessary for the Part D sponsor to notify the pharmacy of the disclosure requirement referenced in this section and the burden on a pharmacy to provide the necessary disclosure to the enrollee. While these requirements are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and/or (b)(3). These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a state or local government does not impose additional burden.

#### **§423.136 Privacy, confidentiality, and accuracy of enrollee records**

(c) and (d) For any medical records or other health and enrollment information it maintains with respect to enrollees, a Part D plan sponsor must maintain the records and information in an accurate and timely manner and provide timely access by enrollees to the records and information that pertain to them.

While these requirements properly maintain and disclose enrollee records are subject to the PRA, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2) and/or (b)(3).

These paragraphs of the PRA regulation state that a usual and customary business activity incurred by persons in the normal course of business, or a requirement sponsored by the Federal government that is also sponsored by a unit of a state or local government does not impose additional burden.

#### **Subpart D--Cost Control and Quality Improvement Requirements for Part D Plans**

##### **§423.153 Drug Utilization Management, Quality Assurance, and Medication Therapy Management (MTM).**

(b) A Part D plan sponsor or MA organization offering an MA-PD plan must provide CMS with information concerning the procedures and performance of its drug utilization management program, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor or MA organization offering an MA-PD plan to provide CMS with information concerning its drug utilization management program, according to guidelines specified by CMS.

We estimate that it will require 102 Part D sponsors, 614 MA organizations, and 55 PACE organizations 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 385.5 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents. The estimated annual cost is \$10,123.23. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (385.5).

(c) A Part D plan sponsor or MA organization offering an MA-PD plan must provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS.

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor or MA organization offering a MA-PD plan to provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS. We estimate that it will require 102 Part D sponsors, 614 MA organizations, and 55 PACE organizations 30 minutes each to provide the required material to CMS for consideration for a total annual burden of 385.5 hours. The increase in total annual burden from the 2006 estimate is due to the increased number of respondents. The estimated annual cost is \$10,123.23. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (385.5).

(d) The previous requirement that a Part D sponsor or MA organization offering an MA-PD plan must provide drug claims data to CCIPs for those beneficiaries that are enrolled in CCIPs in a manner specified by CMS is no longer applicable. CCIPs are now referred to as Medicare Health Support Organizations (“MHSO”). As of November 2006, CMS provided Plans the option to sign a Business Associate Agreement to allow CMS to share prescription drug event data with the appropriate MHSO(s). Entities known as CCIPs will no longer exist. For the PDPs that this requirement applies, the majority have signed this agreement. The burden therefore previously associated with this requirement for the time and effort necessary for each Part D sponsor or MA organization offering an MA-PD plan to provide drug claims data may be deleted.

A Part D sponsor must provide CMS with information regarding the procedures and performance of its MTM program, according to guidelines specified by CMS. We estimate that it will require 102 PDP sponsors and 614 MA organizations, 60 minutes each to provide the required material to CMS for consideration for a total annual burden of 716 hours. The estimated annual cost is \$18,802.16. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (716).

An applicant to become a Part D sponsor must describe in its application how it will take into account the resources used and time required to implement the MTM program it chooses to adopt in establishing fees for pharmacists or others providing MTM services for covered Part D drugs under a prescription drug plan and disclose to CMS upon request the amount of the management and dispensing fees and the portion paid for MTM services to pharmacists and others upon request. Reports of these amounts are protected under the provisions of section 1927(b)(3) (D) of the Act.

The burden associated with this requirement is captured under section 423.265.

#### **§ 423.168 Accreditation organizations.**

(c) An accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis all of the following required by this part.

Since CMS expects to contract with less than 10 organizations on an annual basis, this requirement is not subject to the PRA.

**§423.171 Procedures for approval of accreditation as a basis for deeming compliance.**

(a) A private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

Since CMS expects to less than 10 applicants on an annual basis, this requirement is not subject to the PRA.

**Subpart F--Submission of Bids and Monthly Beneficiary Premiums; Plan Approval**

**§ 423.265 Submission of bids and related information.**

(a) An applicant may submit a bid that meets the requirements set forth in this section and related sections of this regulation, to become a Part D plan sponsor, to become an MA organization offering an MA-PD plan, or to become a PACE organization offering Part D coverage to Part D eligible PACE participants.

The burden associated with this requirement is the time and effort necessary for an entity to submit the required materials to CMS. The information collection instrument, instructions, burden estimates and estimates of participation for Subpart F are included in the referenced OMB approved package OMB # 0938-0944.

## **Subpart G--Payments to Part D plan sponsors and MA-PD Plans For All Medicare Beneficiaries For Qualified Prescription Drug Coverage**

### **§ 423.329 Determination of payment.**

(b) Part D plan contracts must submit data regarding drug claims to CMS that can be linked at the individual level to Part A and Part B data in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 102 Part D plan sponsors contracts and 55 PACE contracts 52 hours to submit the required documentation to CMS for total annual burden of 8,164 hours.

**(ii) MA organizations that offer MA–PD plans to submit data regarding drug claims that can be linked at the individual level to other data that the organizations are required to submit to CMS in a form and manner similar to the process provided under § 422.310 and other information as CMS determines necessary.**

The burden associated with this requirement is the time and effort necessary for MA organizations submit the required claims data to CMS. We estimate that on an annual basis it will take 614 MA contracts 15 hours to submit the required documentation to CMS for total annual burden of 9,210 hours.

### **§ 423.336 Risksharing arrangements.**

(a) A Part D plan sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (b) of this section.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 5 Part D plan sponsors 20 hours to submit the required documentation to CMS for total annual burden of 100 hours.

(c) Within 6 months of the end of a coverage year, the Part D plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take 102 Part D only contract 55 PACE contracts, and 614 MA contract 10 hours per month to submit the required documentation to CMS for total annual burden of 92,520 hours.

### **§ 423.343 Retroactive adjustments and reconciliations.**

(c) Within 6 months of the end of a coverage year, the Part D plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part D only sponsors to submit the required data to CMS. We estimate that on an annual basis it will take 102 Part D Only contracts, 55 PACE contracts and 614 MA contract 10 hours to submit the required documentation to CMS for total annual burden of 7,710 hours.

(d) Within 6 months of the end of a coverage year, the Part D plan must provide the information that CMS requires.

The burden associated with this requirement is the time and effort necessary for Part only sponsors to submit the required cost data to CMS. We estimate that on an annual basis it will take

102 Part D Only contracts, 55 PACE contracts and 614 MA contracts 10 hours to submit the required documentation to CMS for total annual burden of 7,710 hours.

Subpart I--Organization Compliance With State Law and Preemption by Federal Law

**§ 423.410 Waiver of certain requirements to expand choice.**

(e) Under this section a Part D plan sponsor applicant may submit a waiver application to CMS to waive certain state licensure and fiscal solvency requirements in order to contract with CMS.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor applicant to submit a waiver application that meets the requirements of this section. We estimate that on an annual basis it will take 87 waiver applicants 1 hour to submit the required waiver documentation to CMS for total annual burden of 87 hours. This burden is included under the Application PRA package 0938-0936

**Subpart J--Special Part D Rules for Organizations Offering MA Plans and Coordination under the Part D Program**

§ 423.458 Application of Part D rules to MA-PD plans on and after January 1, 2006.

b) Organizations offering or seeking to offer a MA-PD plan may request from CMS in writing waiver or modification of those requirements under this part that are duplicative of, or that are in conflict with provisions otherwise applicable to the plan under Part C.

c) Any entity seeking to offer, sponsor, or administer an employer-sponsored group prescription drug plan may request, in writing, a waiver or modification of additional requirements under this Part that hinder its design of, the offering of, or the enrollment in, such employer-sponsored group prescription drug plan.

d) A cost plan (as defined in 42 CFR 417.401) or PACE organization (as defined in 42 CFR 460.6) that offers qualified prescription drug coverage under Part D may request, in writing, a waiver or modification of those requirements under this part otherwise applicable to cost plans or PACE organizations that are duplicative of, or that are in conflict with, provisions otherwise applicable to cost plans under section 1876 of the Act or PACE organizations or under sections 1894 and 1934 of the Act, or as may be necessary in order to improve coordination of this Part with the benefits offered by cost plans or PACE organizations.

The burden associated with the above three requirements has been included within the PRA package for the Part D applications under 0938-0936.

**§423.464 Coordination of benefits with other providers of prescription drug coverage**

(a) The administrative processes referred to in this section of the regulation were established by CMS in a Part D Manual chapter titled “Chapter 14 – Coordination of Benefit Manual. The PRA package associated with these requirements is PRA 0938-0978.

(f) A Part D sponsor must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under §423.104(d)(5)(iii). To ensure that this requirement is met, A Part D enrollee must disclose all

these expenditures to a Part D plan in accordance with requirements under §423.32(b)(ii). The burden associated with this requirement is the time and effort necessary for a Part D enrollee to disclose all these expenditures to a Part D plan in accordance with requirements under §423.32(b)(ii). The burden associated with this requirement is captured and discussed above under §423.32(b).

### **Subpart K--Application Procedures and Contracts With Part D plan Sponsors**

#### **§ 423.502 Application requirements.**

**(b) In order to become a Part D sponsor, an entity, or an individual authorized to act for the entity (the applicant), must complete, comply with, and submit a certified application in the form and manner required by CMS that meets the requirements set forth in this section.**

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required application materials to CMS. These hours and time frames are all detailed in the Application PRA package 0938-0936.

#### **§ 423.505 Contract provisions**

(d) The Part D sponsor agrees must maintain for 6 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 771 Part D sponsors and MA organizations 52 hours to maintain the required documentation on an annual basis, for total annual burden of 40,092. The estimated annual cost is \$1,052,815.92. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (40092).

(f) The Part D sponsor must submit to CMS certified financial information that must include the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 771 Part D plan sponsors and MA organizations 8 hours to submit the required documentation to CMS for total annual burden of 6168 hours.

The estimated annual cost is \$161,971.68. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (6168).

Section 423.505(k)(5) states that the Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify that the information provided is accurate, complete, and truthful and fully conforms to the requirements in §§423.336 and 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(h)(1).

#### **§ 423.507 Nonrenewal of Contract.**



(a) If a Part D sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in a manner that meets the requirements of this section, each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to submit a notice of nonrenewal to CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

**§423.508 Modification or termination of contract by mutual consent.**

(b) If the contract is terminated by mutual consent, the Part D sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

. Based on our experience with the Part D program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

**The estimated annual cost is \$1,579,223.88. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (771). §423.509 Termination of Contract by CMS.**

(b) If CMS notifies the Part D sponsor in writing 90 days before the intended date of their termination the Part D plan sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination.

The Part D sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D sponsor's service area.

Based on our experience with the Part D program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

**§ 423.510 Termination of contract by the Part D plan sponsor.**

(a) If a Part D sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the Part D sponsor must give advance notice to CMS, its Medicare enrollees, and the general public in a manner that meets the requirements set forth in the section.

Based on our experience with the Part D program CMS does not anticipate that more than 9 of these terminations will occur on an annual basis.

**§ 423.514 Reporting requirements.**

The burden estimate for the reporting requirements is reflected under PRA package OMB #0938-0992.

Subpart L--Effect of Change of Ownership or Leasing of Facilities During Term of Contract

### **§423.551 General provisions**

(c) states that a Part D plan sponsor that has a Medicare contract in effect under §423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The Part D plan sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is the time and effort of the Part D plan sponsor considering or negotiating a change in ownership, to notify CMS and provide the information specified in this section. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.4.

### **§423.552 Novation agreement requirements**

(a) Discusses the conditions for CMS approval of a novation agreement. This paragraph requires the Part D plan sponsor to notify CMS at least 60 days before the date of the proposed change of ownership and requires them to provide CMS with updated financial information and a discussion of the financial solvency impact of the change of ownership on the surviving organization.

The burden associated with this requirement is discussed above in §423.551 of the PRA section.

This paragraph also requires the Part D plan sponsor to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

The burden associated with this requirement is time and effort of the Part D plan sponsor to provide CMS with the required documentation. While this requirement is subject to the PRA, we believe that it would affect less than 10 entities on an annual basis; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

## **Subpart M--Grievances, Coverage Determinations, and Appeals**

### **§ 423.562 General Provisions**

(a) A Part D plan sponsor must ensure that all enrollees receive written information about the grievance, coverage determination, and appeals procedures that are available to them through the Part D plan sponsor and that meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 800 hours.

### **§ 423.564 Grievance procedures.**

(e) The Part D plan sponsor must notify the enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance.

The burden associated with this requirement is the time and effort necessary for Part D

plan sponsors to notify enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan sponsor receives the oral or written grievance. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to meet the notification requirements of this section an annual basis, for total annual burden of 5200 hours.

(g) The Part D plan sponsor must maintain records on all grievances received both orally and in writing, including, at a minimum, the date of receipt, final disposition of the grievance, and the date that the Part D plan sponsor notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 100 Part D plan sponsors 52 hours to maintain the required documentation on an annual basis, for total annual burden of 5,200 hours.

§ 423.568 Standard timeframe and notice requirements for coverage determinations.

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee whenever a coverage determination is unfavorable. We estimate the universe of such determinations to be 140,000 (approximately 80 percent of which will be "exceptions requests" under §423.578). We estimate that it will take 30 minutes to prepare a notice of unfavorable decision. The total estimated annual burden is 56,000 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must notify the enrollee of its determination no later than 72 hours after receipt of the request.

The burden associated with this requirement is the time and effort necessary for the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that approximately 10 percent of coverage determinations will involve payment disputes. Thus, the annual associated burden will be 7000 hours.

(c) The burden associated with requirement is discussed above in §423.568(a).  
**§ 423.570 Expediting certain coverage determinations.**

(c) The Part D plan sponsor must document all oral requests in writing and maintain written and oral request documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis 10 percent of all coverage determinations will be expedited requests. Of the 12,600 requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take 100 Part D plan sponsors 57 hours to maintain the required documentation on an annual basis, for total annual burden of 5700 hours.

(d) If a Part D plan sponsor denies a request for expedited determination, it must give the enrollee prompt oral notice of the denial and subsequently deliver, within 3 calendar days, a written letter that explains the notice requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 1 percent of the expedited requests will be transferred to the standard process. We estimate that it will take each of the 100 Part D plan sponsors 15 minutes to process each of the 126 cases. Thus, it will take Part D plan sponsors 32 hours an annual basis to disclose the information.

**§ 423.572 Timeframes and notice requirements for expedited coverage determinations.**

(a) Except as provided in paragraph (b) of this section, a Part D plan sponsor that approves a request for expedited determination must make its determination and notify the enrollee (and the prescribing physician involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's supporting statement.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee and prescribing physician involved in 11,340. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose adverse coverage determinations. We estimate that approximately 15 percent of the cases (1700) will involve adverse coverage determinations, for a total annual burden of 850 hours. We estimate that it will take 5 minutes for the Part D plan sponsors to disclose favorable decisions for the remaining 9640 cases for a total annual burden of 803 hours.

(b) The burden associated with this requirement is discussed above in §423.572(a).

**§ 423.578 Exceptions process.**

(a) An enrollee, the enrollee's representative, or the enrollee's prescribing physician (on behalf of the enrollee) may file a request for an exception that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plans sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

(b) An enrollee, the enrollee's representative, or the prescribing physician (on behalf of the enrollee) may file an exception request that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for exception. We estimate it will require an individual 30 minutes to provide the request and that that the 100 Part D plan sponsors will receive 112,000 requests on an annual basis. Therefore, we estimate a total annual burden of 56,000 hours.

A Part D plan sponsor may require a written supporting statement from the enrollee's prescribing physician that the requested prescription drug is medically necessary to treat the enrollee's disease or medical condition. The Part D plan sponsor may require the prescribing physician to provide additional supporting medical documentation as part of the written follow-up.

The burden associated with this requirement is the time and effort necessary for a prescribing

physician to submit the required documentation to the Part D plan sponsor. We estimate it will require a prescribing physician 15 minutes to provide the supporting documentation and that the 100 Part D plan sponsors will make 5,600 requests on an annual basis. Therefore, we estimate a total annual burden of 1400 hours.

**§ 423.580 Right to a redetermination.**

Section 423.580 provides information on the ways for an enrollee to seek a redetermination. The burden associated with a reconsideration is exempt from the PRA as stipulated under 5 CFR 1320.4.

**§ 423.2262 Review and distribution of marketing materials.**

Section 423.2262(a)(1)(i) requires the Part D sponsor to submit the marketing material or form to CMS for review under the guidelines in §423.2264.

The burden associated with these requirements is the time and effort put forth by the Part D sponsor to submit the marketing materials to CMS and to provide certification. We estimate it would take one Part D sponsor (720 minutes/12 hours) to comply with this requirement. We estimate 87 Part D sponsors would be affected annually by this requirement; therefore, the total annual burden associated with this requirement is 1044 hours.

**§ 423.2264 Guidelines for CMS review and notification.**

Section 423.2264 reads that in reviewing marketing material or enrollment forms under §423.2262, CMS determines (unless otherwise specified in additional guidance) that the marketing materials provide, in a format (and, where appropriate, print size), and using standard terminology that may be specified by CMS, the following information to Medicare beneficiaries interested in enrolling must consist of:

(a) Adequate written description of rules (including any limitations on the providers from whom services can be obtained), procedures, basic benefits and services, and fees and other charges.

(b) Adequate written explanation of the grievance and appeals process, including differences between the two, and when it is appropriate to use each.

(c) Any other information necessary to enable beneficiaries to make an informed decision about enrollment.

(d) Notify the general public of its enrollment period in an appropriate manner, through appropriate media, throughout its service area.

(e) Include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS, that CMS also may refuse to renew the contract, and that termination or non-renewal may result in termination of the beneficiary's enrollment in the Part D plan. In addition, the Part D plan may reduce its service area and no longer be offered in the area where a beneficiary resides.

(f) Are not materially inaccurate or misleading or otherwise make material misrepresentations.

(g) For markets with a significant non-English speaking population, provide materials in the language of these individuals.

The burden with these guidelines is the time and effort put forth by the Part D plan to provide adequate written descriptions of rules, of the grievance and appeals process, and any other information necessary to enable beneficiaries to make an informed decision about enrollment. It also requires the Part D plan to notify the general public of its enrollment period in an appropriate

manner and include in the written materials notice that the Part D plan is authorized by law to refuse to renew its contract with CMS. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

#### **§423.2268 Standards for Part D Marketing**

Section 423.2268 (g) states Part D organizations cannot market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment.

The burden associated with this requirement is the time and effort put forth by the Part D organization to document a beneficiary's signed acknowledgement confirming the specific types of choices that the marketing representative is authorized to discuss. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

#### **§ 423.2272 Licensing of marketing representatives and confirmation of marketing resources.**

Section 423.2272(b) requires the Part D organization to establish and maintain a system for confirming that enrolled beneficiaries have in fact enrolled in the PDP and understand the rules applicable under the plan.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to establish and maintain such a system. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

#### **§ 423.2274 Broker and agent commissions and training of sales agents.**

Section 423.2274 requires the Part D sponsor to train and test agents selling Medicare products concerning Medicare rules and regulations specific to the plan products they intend to sell.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to provide training and test agents. While there is burden associated with this requirement, we feel the burden associated with these requirements is exempt from the requirements of the Paperwork Reduction Act of 1995 (PRA) as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement would be incurred by persons in the normal course of their activities.

Section 423.2274(d) states that upon CMS's request, the Part D sponsor must provide CMS the information necessary for it to conduct oversight of marketing activities. We estimate 87 Part D sponsors would be affected annually by this requirement. The burden associated with this requirement is the time and effort put forth by the Part D sponsor to produce the information requested by CMS. The estimate average amount of time it would take one Part D sponsor to comply with this requirement is 49 hours; therefore, the total annual burden associated with this

requirement is 4,263 hours. Listed below is a detailed burden analysis.

Completing Attachment 1 through 3 for organizations w health plans in 2006 will take 48 hours. We assume that all the plans who can avail themselves to Option One will do so.

1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.

5 hours – collect and submit compensation structures required under Attachments 2a and 2b

10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.

2 hours – calculate and submit Year 2009 renewal schedules using Option One.

15 hours – derive values for actual initial compensations for years 2006 through 2008.

15 hours – derive values for expected compensation to be paid over life of schedule for years 2006 through 2008.

48 hours – TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2007 will take 54 hours.

1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.

5 hours – collect and submit compensation structures required under Attachments 2a and 2b

10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.

16 hours – calculate and submit Year 2009 renewal schedules using Option Two.

10 hours – derive values for actual initial compensations for years 2007 through 2008.

10 hours – derive values for expected compensation to be paid over life of schedule for years 2007 through 2008.

54 hours TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2008 will take 44 hours.

1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.

5 hours – collect and submit compensation structures required under Attachments 2a and 2b

10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.

16 hours – calculate and submit Year 2009 renewal schedules using Option Two.

5 hours – derive values for actual initial compensations for year 2008.

5 hours – derive values for expected compensation to be paid over life of schedule for year 2008.

44 hours TOTAL BURDEN

Completing Attachment 1 through 3 for organizations w new health plan types in 2009 will take 32 hours.

1 hour -- complete and submit CEO signatures on Attachments 1a and 1b.

5 hours – collect and submit compensation structures required under Attachments 2a and 2b

10 hours – collect and submit names of marketing contracting organizations, as well as counts of agents, by schedule under Attachments 2a and 2b.

16 hours – calculate and submit Year 2009 renewal schedules using Option Two.

32 hours TOTAL BURDEN

For PDPs, to fulfill this requirement the average burden would be 49 hours, for a total burden across all PDP contracts of 4263 hours. The cost would be \$54.98 X 4263 hours, for a total cost of \$234,379.

**§ 423.582 Request for a standard redetermination.**

**(a) An enrollee must ask for a redetermination by making a written request with a Part D plan sponsor that made the coverage determination. The Part D plan sponsor may adopt a policy for accepting oral requests.**

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for redetermination. We estimate that approximately 15 percent of the 140,000 coverage determinations will be adverse. Of those 21,000 cases, we estimate that approximately 50 percent will be appealed. We further estimate it will require an individual 30 minutes to provide the request and that the 100 Part D plan sponsors will receive 9,450 standard requests on an annual basis. Therefore, we estimate a total annual burden of 4,725 hours.

(c) If the 60-day period in which to file a request for a redetermination has expired, an enrollee may file a request for redetermination and extension of time frame with the Part D plan sponsor.

The burden associated with this requirement is the time and effort necessary for an individual to submit a request for extension of redetermination. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 100 requests on an annual basis. Therefore, we estimate a total annual burden of 2500 hours.

**(d) The person who files a request for redetermination may withdraw it by filing a written request for withdrawal at the location listed in paragraph (a) of this section.**

The burden associated with this requirement is the time and effort necessary for an individual to submit a withdrawal request. We estimate it will require an individual 15 minutes to provide the request and that each of the 100 Part D plan sponsors will receive 5 requests on an annual basis. Therefore, we estimate a total annual burden of 125 hours.

**§ 423.584 Expediting certain redeterminations.**

(c) The Part D plan sponsor must document all oral requests in writing, and maintain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to maintain the required documentation outlined in this section. We estimate that on an annual basis, 10 percent of the 10,500 redeterminations will be expedited requests. Of the 1,050 expedited requests, we estimate that approximately 90 percent will be oral requests. Thus, it will take the 100 Part D plan sponsors approximately 5 hours to maintain the required documentation on an annual basis, for total annual burden of 500 hours.

(d) If a Part D plan sponsor denies a request for expedited redetermination, it must give the enrollee prompt oral notice, and subsequently deliver, within 3 calendar days, a written letter that explains the requirements set forth in this section.



The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that 10 percent of the expedited requests will be transferred to the standard process. We further estimate that it take each of the 100 Part D plan sponsors 15 minutes to process each of the 105 cases to disclose the information for a total annual burden of 26 hours.

**§ 423.590 Timeframes and responsibility for making redeterminations.**

(a) When a party makes a request for a drug benefit, the Part D plan sponsor must notify the enrollee in writing of its redetermination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for a standard redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes to disclose the information for a total annual burden of 4,725 hours.

(b) When a party makes a request for payment, the Part D plan sponsor must issue its redetermination no later than 7 calendar days from the date it receives the request for a standard redetermination. We estimate that 10 percent of the 9,450 standard redetermination requests will involve payment disputes.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to an enrollee. We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 473 hours.

(d) A Part D plan sponsor that approves a request for expedited redetermination must complete its redetermination and give the enrollee (and the prescribing physician involved, as appropriate), notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request for an expedited redetermination.

The burden associated with this requirement is the time and effort necessary for each of the 100 Part D plan sponsors to disclose the necessary information to 895 enrollees (and the prescribing physicians involved, as appropriate). We estimate that it will require each of the 100 Part D plan sponsors 30 minutes on an annual basis to disclose the information for a total annual burden of 448 hours.

**Subpart N—Medicare Contract Determinations and Appeals**

This Subpart deals with Contract Determinations and Appeals; therefore, the information collection requirements referenced in this Subpart are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.

**Subpart O--Intermediate Sanctions**

**§423.756 Procedures for imposing sanctions.**

(a) Before imposing the intermediate sanctions specified in this section, CMS will allow the Part D plan sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the Part D plan sponsor to provide the evidence if the Part D plan sponsor sends a written request providing a

credible explanation of why additional time is necessary.

These information collection requirements are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) during the conduct of an administrative action, investigation, and/or audit.  
Subpart P--Premiums and Cost-Sharing Subsidies for Low-Income Individuals

#### **§423.774 Eligibility determinations, redeterminations and applications.**

Paragraph (d) of this section discusses the application requirements for individuals applying for low-income subsidy. This paragraph states that individuals applying for low-income subsidy, or a personal representative applying on the individual's behalf, must complete all required elements of the application, provide any statements from financial institutions, as requested, to support information in the application, and certify, as to the accuracy of the information provided on the application form.

The burden associated with this requirement is the time and effort for the individual or personal representative applying on the individual's behalf, to complete the low-income subsidy application, provide financial statements as requested and to certify that the information provided is accurate. These collection requirements are subject to the PRA; however, the burden associated with these requirements is currently approved under OMB# 0938-0467 with a current expiration date of October 31, 2005. We will revise this currently approved PRA package to incorporate the burden being imposed on new enrollees. We estimate that this requirement will impose a burden on 4.5 million new enrollees for a total additional burden of 750,000 hours annually (4.5M X 10 minutes).

#### **§423.800 Administration of subsidy program.**

Paragraph (b) of this section requires the Part D plan sponsor offering the Part D plan, or the MA organization offering the MA-PD plan, to reduce the individual's premiums and cost-sharing as applicable and provide information to CMS on the amount of such reductions, in a manner determined by CMS. This paragraph also requires the Part D plan sponsor offering the Part D plan to maintain documentation to track the application of the low-income cost-sharing subsidies to be applied to the out-of-pocket threshold.

The burden associated with these requirements is the time and effort for the Part D plan sponsor offering the Part D plan to provide information to CMS and to maintain documentation. We estimate that it will take each of the 771 Part D sponsors approximately 52 hours on an annual basis to provide the information to CMS. We also estimate that it will take approximately 26 hours for each of the 771 entities to maintain the information for tracking purposes. Therefore, we estimate that it will take approximately 60,138 total hours annually to comply with these requirements

Subpart Q--Guaranteeing Access to a Choice of Coverage

#### **§423.859 Assuring access to a choice of coverage.**

(c) states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in an area such, as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D in order to provide qualified

prescription drug.

The burden associated with this requirement is the time and effort for the Part D plan to make a request of waiver or modification to CMS. We estimate that approximately 2 Part D plans will request a waiver or modification on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

**§423.863 Submission and approval of bids.**

(a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more Part D plan regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders.

The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid that meets the requirements of the section and related sections.

We estimate as an upper limit that approximately 20 fallback entities will submit a bid every three years. We also estimate that it will take each fallback entity approximately 80 hours to complete and submit the bid to CMS. Therefore, we estimate it will take a total of  $(20 * 80) / 3 = 533.33$  hours on an annual basis to comply with this requirement.

(b) discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts.

The burden associated with this requirement is the time and effort for the fallback entities to enter into a contract with CMS that meets the requirements of this section and related sections.

We estimate, again as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

**§423.871 Contract terms and conditions.**

(f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section.

The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

**Subpart R—Payments to Sponsors of Retiree Prescription Drug Plans**

**§ 423.884 Requirements for qualified retiree prescription drug plans.**

(a),(b), (c),and (d) In order to qualify for the retiree drug subsidy, the employer or union sponsor shall file an annual application with CMS that meets the requirements of this section and related sections, for each qualified retiree prescription drug plan maintained, including an attestation as to actuarial value.

The burden associated with this requirement is the time and effort necessary for an entity to submit the application to CMS. The requirements of this part state that an application must provide sponsor and plan identification information, together with an actuarially-certified attestation that the actuarial value of the retiree prescription drug coverage in each plan (benefit

option) is at least equal to the actuarial value of standard Medicare Part D prescription drug coverage in accordance with actuarial guidelines established by CMS in accordance with generally accepted actuarial principles. If there is a change during the year that materially affects the actuarial value of their drug coverage, sponsors will need to submit an updated attestation. Sponsors will also be required to collect identifying information on their qualifying covered retirees and submit this information with their application, along with a signed sponsor agreement. If we determine that a sponsor of a retiree prescription drug program meets all of the requirements of this section, we will send to the sponsor a written notification regarding the sponsor's eligibility to receive a subsidy payment along with a list of qualified retirees that has been verified with the Medicare Beneficiary Database (MBD).

The Retiree Drug Subsidy program application for plan sponsors, the instructions for completing the application, and all corresponding burden estimates, estimates of participation, and economic impact statements are included under the following separate information collection instrument: OMB# 0938-0957, Retiree Drug Subsidy (RDS) Application and Instructions. RDS plan sponsors are exempt from this requirement since CMS is notified of their creditable coverage status through the RDS application accounted for under OMB 0938-0990.

**§ 423.888 Payment methods, including provision of necessary information**

(b) and (c) To receive payment under this section, each qualified entity must submit information in a form and manner and at such times provided in this paragraph and under other guidance specified by CMS, by the sponsor or any party designated the sponsor.

If a sponsor elects to receive monthly or quarterly retiree subsidy payments or an interim annual retiree subsidy payment, the plan sponsor must submit aggregated gross cost data or estimated premium amounts costs under the cost threshold, costs over the cost limit, an estimate of the expected rebates and other price concessions, and any other data CMS may require upon submission of data for payment at each of the time intervals elected by the sponsor, with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit actual, not estimated, amounts for the categories of costs in the preceding sentence within 15 months after the end of the plan year, or by some other date established by CMS. In addition, plan sponsors are required to provide on a monthly basis an update to their retiree list if information associated with their retirees changes.

The Retiree Drug Subsidy program payment request process, the instructions for completing a payment request, and all corresponding burden estimates, estimates of participation, and economic impact statements are included under the following separate information collection instrument: OMB# 0938-0977, Retiree Drug Subsidy Payment Request and Instructions.

**§ 423.892 Change in Ownership**

(c) A sponsor who is contemplating or negotiating a change of ownership must notify CMS. We estimate that approximately 5 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 50 entities (1 percent of 5,000) about one hour (6030 minutes) to submit the required notification to CMS, for a total of approximately 50 burden hours.

**Subpart S--Special Rules for States—Eligibility Determinations for Subsidies and General Payment Provisions.**

#### **§423.904 Eligibility determinations for low-income subsidies.**

Paragraph (b) of this section states the State agency must inform CMS of cases where eligibility is established or redetermined.

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately 11,220 annual hours. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

Paragraph (d) of this section requires States to make available--low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

The burden associated with the requirement on States to make available the information specified in this section is subject to the PRA; however, we believe the burden for this requirement to be a reasonable and customary business practice; therefore, imposes no additional burden on the States.

The burden associated with the requirement on States to require the applicant of the low-income subsidy to complete all required elements, to provide documents, and to certify as to the accuracy of the information is subject to the PRA; however, the burden associated with this requirement is discussed in §423.774 above.

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately 1,020 annual hours. Since it is difficult to determine at this time the volume of information CMS will request, we are estimating that it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

#### **§423.907 Treatment of Territories**

Paragraph (a) of this section discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) of this section describes what a plan must include.

The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. While this requirement is subject to the PRA, we estimate that this requirement would affect only 5 territories; therefore, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

#### **§423.910 Requirements.**

(c) This subpart sets forth the requirements for State contributions for Part D drug benefits based on dual eligible drug expenditures. It requires States to submit MSIS data to provide accurate and complete coding to identify the numbers and types of Medicaid and Medicare dual eligibles in their MSIS data submittals.

The burden associated with the requirement on States to provide accurate and complete coding in their MSIS data submittals is subject to the PRA; however, this requirement is already approved under OMB #0938-0502 with a current expiration date of January 31, 2006.

(d) The subpart also requires States to submit an electronic file, in a manner specified by the Secretary, identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage who is also determined to be full benefit eligible by the State for full Medicaid benefits.

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of 6,120 hours on an annual basis. The estimated annual cost is \$160,711.20. This is based upon the hourly rate at the GS-11/step 6 \$26.26 multiplied by the number of burden hours (6120).

### **Subpart T-Financial Relationships Between Physicians and Entities Furnishing Designated Health Services.**

Subpart T does not contain any requirements subject to the PRA.

### **13. Capital Costs**

All the organizations are going concerns and there are no additional capital or equipment costs resulting from the collection of information. Also refer to “Section V” (Impact Analyses) of the preamble of attached regulation for more information related capital costs.

14. **Cost to the Federal Government**

There will be no costs to the Federal Government.

15. **Program Changes**

The language under #12 (Burden Estimates) associated with Subpart R has been updated. For 423.884 and 423.888, references to other OMB information collection instruments have been added. The information collection instruments, instructions, corresponding burden estimates, estimates of participation, and economic impact statements for these sections are included in the referenced OMB-approved packages (OMB# 0938-0957 and OMB# 0938-0977).

The burden estimate associated with Subpart R, Section 423.892, has been significantly reduced based on actual experience since these estimates were last published. Significantly fewer plan sponsors have reported a change in ownership to CMS than was originally estimated. In addition, total plan sponsor participation in the program has been adjusted to reflect actual experience.

This package has been revised to include the new requirements in proposed rule CMS-4131-P.

16. **Publication and Tabulation Dates**

There are no publication or tabulation dates. Subsequent PRA packages may include these requirements, which will be addressed, as required, when packages are submitted to OMB for approval.

17. **Expiration Date**

This information collection contains very few forms; specifically, the forms are associated with the information collection requirements contained in §423.2274. Where applicable, CMS will display the expiration dates on the forms.

18. **Certification Statement**

There are no exceptions to the certification statement.

**C. Collections of Information Employing Statistical Methods**

Not applicable.