Supporting Statement Part A
Medicare Prescription Drug Benefit Program
CMS-10141, OCN 0938-0964

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 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 would be available to beneficiaries beginning on January 1, 2006.

Generally, coverage for the prescription drug benefit is provided under private prescription drug plans (PDPs), which will offer only prescription drug coverage, or through Medicare Advantage prescription drug plans (MA-PDs), which 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-PDs or PDPs, except fallback PDPs, 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.

A. 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 potential and current 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 collected less frequently, CMS would not have access to the data necessary to administer the Part D program. Some of the consequences would be improper or erroneous payment to Part D plans, improper enrollment of beneficiaries in a Part D organization, release of misleading information regarding the 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 60-day Federal Register notice published on October 4, 2013 (78 FR 61848). No comments were received.

No further outside consultations were necessary for this revised information collection, since the program became available to beneficiaries beginning January 1, 2006. Therefore, the revisions to the collection are based on program experience.

Public meetings were held in February 2005 and written comments were received which were in turn utilized by CMS during the regulation's drafting stage. Also, as necessary, CMS consulted with technical experts and industry and beneficiary advocates to obtain their opinions on the provisions of the statute; two examples involved long term care policy and coordination of benefits and the facilitation of plan tracking of Part D enrollees' TrOOP. 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 implemented the final rule.

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, the purpose of which is the broad public dissemination of 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)

BURDEN TABLE

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.32(a) and (b)	Individual	4,000,000	0.5	1	4,000,000	2,000,000
423.32(b)	Individual	2,600,000	0.017 (1 min)	1	2,600,000	44,200
423.32(d)	Private Sector	852	3	2	1,704	5,112
			0.017 (1 min)	4,695	4,000,000	68,000
423.34(e)	Individual	130,000	0.25	1	130,000	32,500
	Private Sector	852	0.25	153	130,000	32,500
423.36(b)	Private Sector	852	1.017	676.2	576,100	10,646
423.44(b)	Private Sector	852	1	1	852	852
			0.1 (6 min)	176.1	150,000	15,000
			1	1	852	852
			0.017 (1 min)	4.7	4,000	68
			1	1	852	852
			0.1 (6 min)	4.4	3,750	375
423.46(b)	Private Sector	852	0.25	586.9	500,000	125,000
423.46(d)	Private Sector	852	0.083 (5 min)	586.9	500,000	41,667
423.48	Private Sector	852	2	1	852	1,704
423.56(f)	Private Sector	85,635	1	1	85,635	85,635

			1.083	1	85,635	87,295
		856	2	1	852	1,712
	Individual	100,000	0.25	1	100,000	25,000
423.104(g)	Private Sector	852	10	1	852	8,520
423.120(b)	Private Sector	852	2	1	852	1,704
			40	1	852	34,080
			0.083 (5 min)	1	19,000,000	1,577,000
423.128(a)	Private Sector	745	200	1	745	149,000
423.128(e)	Private Sector	745	160	1	745	119,200
423.153(b)	Private Sector	852	0.5	1	852	426
423.153(c)	Private Sector	852	0.5	1	852	426
423.329(b)	Private Sector	162	52	1	162	9,568
		668	15	1	668	10,020
423.336(a)	Private Sector	5	20	1	5	100
423.336(c)	Contracts	830	10/month	12	9,960	104,640
423.343(cc)	Contracts	830	10	1	830	8,720
423.343(d)	Contracts	830	10	1	830	8,720
423.505(d)	Private Sector	852	52	1	852	44,304
423.505(f)	Private Sector	852	8	1	852	6,816
423.562(a)	Private Sector	424	8	1	424	3,392
423.564(e)	Private Sector	424	0.5	31.1	13,200	6,600
			0.25	280.2	118,800	29,700
423.564(g)	Private Sector	424	52	1	424	22,048
423.568(a)(3)	Private Sector	424	0.05 (3 min)	4333.7	1,837,500	91,875
423.568(b), (c), (d), and (f)	Private Sector	424	0.25	2686.9	1,139,250	284,813

			0.25	5980.5	2,535,750	633,938
423.570(c)(2)	Private Sector	424	0.05 (3 min)	2744.7	1,163,750	58,188
423.570(d)	Private Sector	424	0.25	28.9	12,250	3,063
423.572(a) and (c)	Private Sector	424	0.25	2859.1	1,212,750	303,188
423.578(a) and (b)	Individual	3,185,000	0.25		3,185,000	796,250
	Private Sector		0.25		2,388,750	597,188
423.800(b)	Private Sector	852	78	1	852	66,456
423.892(cc)	Private Sector	50	1	1	50	50
423.904(b)	State	51	10/month	12,000	600,000	6,120
			20	1	51	1,020
423.910(d)	State	51	10/month	12	51	6,120
					TOTAL	**7,572,223**

PROVISIONS

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 (0.5 hours) to complete and submit the required application to the Part D plan. Since the inception of the Part D program in 2006, more than 30 million individuals are enrolled in the program. Once enrolled, individuals are not required to complete an enrollment application to remain enrolled in their chosen plan year-to-year. Generally individuals are limited to changing Part D plans during the annual coordinated election period, and enrollment data indicates that individuals typically stay with a plan once enrolled. In 2012, about 700,000 individuals newly enrolled or switched plans during the annual coordinated election period. Therefore, it is estimated that a total of 1 million individuals may change their Part D plans annually and that 3 million new beneficiaries will be making first time enrollments into Part D plans. **The total burden is calculated it be 4 million enrollments x 0.5 hours = 2,000,000**

hours. The change in burden is due to decreases in the number of individuals enrolling in 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 plan sponsor must 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. All new enrollments require this information as part of the enrollment application (burden reflected under section 423.32(a)), however plan sponsors may request currently enrolled members to provide this information upon indication of other insurance.

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 44,200 hours. **We estimate that 2.6 million beneficiaries will need 1 minute (0.017 hours) to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of 44,200 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. Every enrollment request requires a response from the Part D plan so that the individual knows if they will be covered under the plan. There are approximately 852 Part D plan sponsors in 2014. Each Part D plan creates the disclosure notices, and most plans continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 3 hours to produce each notice –an acceptance and a denial notice. 852 plan sponsors x (3 hours x 2 notices) = 5,112 hours. We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) to assemble and disseminate the proper notice for each of the enrollment requests received annually. 4 million requests x 0.017 hours (1 minute each) = 68,000 hours. **The total number of hours is 73,112 or 85.812 hours per sponsor annually.** The estimated annual cost is $2,273,783. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (73,112). The change in burden is due to adjustments in the number of Part D plans and errors in calculations in the number of responses from the last submission.

§423.34 Enrollment of full-benefit dual eligible individuals.

Section 423.34(e) states that a full-benefit dual eligible beneficiary may decline enrollment

in a Part D plan or may enroll in a plan different than the plan into which CMS placed them.

The burden associated with this requirement is the time and effort put forth by the individual to actively decline enrollment or to actively enroll in a new, and for plans to process the enrollments and disenrollments. We estimate it would take an individual about 15 minutes (0.25 hours) to, either contact the plan to disenroll or contact the new plan to enroll (resulting in an automatic disenrollment from the plan into which the person was enrolled by CMS). Beneficiaries can contact plans in a number of ways, with varying amounts of time needed for the contact. A beneficiary would need to take this time only once. There are on average approximately 130,000 new full dual choosers each year so we estimate that it takes full dual beneficiaries 32,500 hours a year to disenroll or enroll (causing a disenrollment) each year. We further estimate the same amount of time for plans to receive and process these enrollments/disenrollments. **The total number of hours is 65,000 (32,500 hours for the full dual beneficiaries and 32,500 hours for the 852 Part D plan sponsors.** The estimated annual cost is $1,017,575. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (32,500) for plan sponsors.

§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, whether it is the result of the individual leaving the Part D program or switching plans during a valid enrollment period. 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. There are approximately 852 Part D plan sponsors in 2014. Each Part D plan creates the disclosure notice, and most plans continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 1 hour to produce the notice. 852 plan sponsors x 1 hour = 852 hours. We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. 576,100 notices x 0.017 hours (1 minute each) = 9,794 hours. **The total number of hours is 10,646 or 12.495 hours per sponsor annually.** The estimated annual cost is $333,326. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (10,646).

§ 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 or 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 premiums following a minimum 2-month grace period and 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 effectuate the disenrollment and disclose to an individual the notice of disenrollment. There are approximately 852 Part D plan sponsors in 2014. Each Part D plan creates the disclosure notice, and most plans continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 1 hour to produce the notice. 852 plan sponsors x 1 hour = 852 hours. We estimate that it will take a Part D plan 5 minutes (0.083 hours) to submit the required transaction to CMS for each occurrence and 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. In recent years, there has been an increase in the number of plans which disenroll for failure to pay premiums. We estimate that on an annual basis 150,000 individuals will be disenrolled for failure to pay premiums. 150,000 notices x 0.1 hours (6 minutes each) = 15,000 hours. **The total number of hours is 15,852 or 18.605 hours per sponsor annually.** The estimated annual cost is $496,326. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (15,852).

Following the enactment of section 3308 of the Affordable Care Act in 2011 which required additional premium amounts to be paid directly to the government by higher-income individuals when enrolled in Part D, CMS may disenroll individuals who do not pay their additional premium amounts, also known as Part D Income Related Monthly Adjustment Amount (Part D-IRMAA), to the government within a 3-month grace period. If payment is not received timely, CMS processes the disenrollment and notifies Part D plans of the involuntary disenrollment, and the plan is required to notify their member of the disenrollment from their plan.

The burden associated with this requirement is the time and effort for the Part D plan sponsor to disclose to an individual the notice of disenrollment. There are approximately 852 Part

D plan sponsors in 2014. Each Part D plan creates the disclosure notices, and most plans continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 1 hour to produce the notice. 852 plan sponsors x 1 hour = 852 hours. We estimate that it will take a Part D plan 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. We estimate that on an annual basis 4,000 individuals will be disenrolled for failure to pay Part D-IRMAA. 4,000 notices x 0.017 hours = 68 hours. **The total number of hours is 920 or 1.079 hours per sponsor annually.** The estimated annual cost is $28,805. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (920).

An individual who is disenrollment for non-payment of premiums or Part D-IRMAA may be reinstated by CMS if the individual shows good cause for not paying premiums timely. In this process, CMS determines if good cause is met based on the individual's request for review and attestation of the unexpected and unforeseen event. Should an individual receive a favorable determination, the payment of all overdue premiums must be paid to the plan and CMS as applicable. Individuals are notified of the plan premium amount owed for reinstatement by the Part D sponsor. CMS notifies individuals of any Part D-IRMAA amounts owed to the government.

The Part D plan sponsor burden associated with this requirement is the time and effort for the Part D plan sponsor to disclose to an individual the notice of the owed plan premium amount required for reinstatement. There are approximately 852 Part D plan sponsors in 2014. Each Part D plan creates the disclosure notices, and most plans continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 1 hour to produce the notice. 852 plan sponsors x 1 hour = 852 hours. We estimate that it will take a Part D plan 5 minutes (0.083 hours) to compile the arrearage information and 1 minute (0.017 hours) to assemble and disseminate the notice for each favorable determination. We estimate that on an annual basis 3,750 individuals will request and receive favorable good cause determinations. 3,750 notices x 0.1 hours (6 minutes) = 375 hours. **The total number of hours is 1,227 or 1.44 hours per sponsor annually.** The estimated annual cost is $38,417. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (1,227).

In addition, we estimate that on an annual basis 200 individuals will also be required to pay arrearages for Part D-IRMAA to CMS in order to be reinstated. **We estimate that it will take a CMS staff person 5 minutes (0.083) to compile the arrearage information and 1 minute (0.017 hours) to assemble and disseminate the notice for each Part D-IRMAA favorable determination. 200 notices x 0.1 hours (6 minutes) = 20 hours.** The estimated annual cost is $698. This is based upon the hourly rate at the GS-11/step 6 $34.92 multiplied by the number of burden hours (20).

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. **Based on actual experience, CMS receives approximately 1-2 total requests for involuntary disenrollment due to disruptive behavior annually. Thus, the burden to Part D plan sponsors is negligible.**

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. There are approximately 852 Part D plan sponsors in 2014. To comply with this requirement, Part D sponsors would expend 15 minutes (0.25 hours) per new Part D enrollee to obtain the information and report it to CMS for calculation of the late enrollment penalty, if one is required. We estimate that on an annual basis approximately 500,000 new Part D enrollees will need to provide this information. **Therefore the total annual burden associated with this requirement will be 500,000 new enrollees x 0.25 hours (15 minutes) = 125,000 hours.** The estimated annual cost is $3,913,750. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (125,000).

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 (0.083 hours) 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 for all new Part D enrollees.** The estimated annual cost is $1,304,583. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (41,667).

§423.48 Information about Part D.

Each Part D plan must 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 852 Part D sponsors 2 hours to submit the required documentation to CMS for a total annual burden of 1,704 hours per sponsor.** The increase in total annual burden from the 2012 estimate is due to the increased number of respondents.

The estimated annual cost is $53,353. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (1,704).

§ 423.50

The September 18, 2008, final rule (CMS 4131-F) removed section 423.50. The provisions from that section were moved and expanded into 423 Subpart V; the requirements are located now in §423.2262(a)(1)(i).

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

(f) 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 October 15 of each year, as defined in 423.38(b); or (4) upon request by the individual. Entities are permitted to provide notices of creditable and non-creditable status with other information materials distributed to beneficiaries by that organization (rather than separately), so that burden for this requirement is reduced.

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. We estimate that it will require 85,635 entities to provide notices in existing plan materials and separate notices (including initial notices to new beneficiaries, annual notices prior to the ACEP, and notices of changes in creditable coverage status), as well as additional separate notices to be provided to individuals upon request. We estimate that it will take each entity approximately 1 hour to produce the disclosure notice. We further estimate that, on average, it will take each entity a negligible amount of time to deliver each notice, since they will be incorporating notices into existing plan materials that are already provided to beneficiaries. **The total burden for entities is 85,635**

hours. The estimated annual cost is $2,681,232. This is based upon a 2012 national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (85,635).

While, it is unknown exactly how many individuals will request a separate copy, we estimate that this would be approximately 20,000 and that each entity will spend approximately 1 hour developing a stand-alone notice for use during the year and 5 minutes (0.083 hours) to assemble and disseminate each requested notice. The burden for developing the stand-alone notice is 85,635 entities x 1 hour = 85,635 hours. The burden for providing the stand-alone notice to individuals requesting separate notification is 20,000 requests x 0.083 hours (5 minutes) = 1,660 hours annually. **The total burden for entities is 87,295 hours.** The estimated annual cost is $2,733,206. This is based upon a 2012 national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (87,295).

In addition, we estimate that approximately 1 percent of the entities may have a change in their creditable coverage status during the year. This would result in approximately 856 entities that would be required to send a disclosure to Medicare Part D eligible individuals enrolled in their organization. We estimate that plans would spend 2 hours each to develop the notification and disseminate the information in their plan materials. **The total burden is calculated as 856 entities x 2 hours = 1,712 hours.** The estimated annual cost is $53,603. This is based upon a 2012 national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (1,712).

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 (0.25 hours) to apply to CMS, for a total of 25,000 hours.**

(e) 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 OMB 0938-1013 (CMS-10198).**

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 852 respondents 10 hours to submit the required documentation to CMS for total annual burden of 8,520 hours.** The estimated annual cost is $266,761. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (8,520).

§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 852 respondents 2 hours each to capture and retain the required documentation on an annual basis for total annual burden of 1,704 hours.** The increase in total annual burden from the previous estimate is due to the increased number of respondents. The estimated annual cost is $53,352. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (1,704).

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 has already created disclosure notices for mass mailings, we estimate that on an annual basis it will take on average, 852 respondents 40 hours to disclose the required notice for a total annual burden of 34,080 hours. The decrease in total annual burden from the estimate previously reported is due to the decreased number of respondents. The estimated annual cost is $1,067,045. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (34,080).

(b)(3)(iv) requires sponsors to provide enrollees with appropriate notice regarding their transition process within three business days after providing a temporary supply of non-formulary Part D drugs (including Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy under a sponsor's utilization management rules). The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to

provide a notice to beneficiaries regarding the transition process. **We estimate this will result in 19 million notices that would take an average of 5 minutes (0.083 hours) to prepare. Thus, we estimate the total burden to be 1,577,000 hours.** The increase in burden hours from the previously reported estimate is based on the number of actual transition fills reported by Part D sponsors. The estimated annual cost is $49,375,870. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (1,577,000).

(c)(1) 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 745 respondents 80 hours on an annual basis to prepare the plan materials. We further estimate that, on average, it will require each entity 120 hours on an annual basis to disseminate the required materials to enrollees and eligible individuals for a total annual burden of 149,000 hours.** The decrease in total annual burden from the previously reported estimate is due to the increased number of respondents. The estimated annual cost is $4,665,190. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (149,000).

(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 745 respondents 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 119,200 hours.** The decrease in total annual burden from the previously reported estimate is due to the decreased number of respondents. The estimated annual cost is $3,732,152. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (119,200).

§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 852 respondents 30 minutes (0.5 hours) each to provide the required material to CMS for consideration for a total annual burden of 426 hours.** The decrease in total annual burden from the previously reported estimate is due to the decreased number of respondents. The estimated annual cost is $13,338. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (426).

(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 852 respondents 30 minutes (0.5 hours) each to provide the required material to CMS for consideration for a total annual burden of 426 hours.** The decrease in total annual burden from the previously reported estimate is due to the decreased number of respondents. The estimated annual cost is $13,338. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (426).

(d) For an applicant to become a Part D sponsor, the applicant 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 and reflected in OMB #0938-0944.**

§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 contract with 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 85 Part D plan sponsors contracts and 77 PACE contracts 52 hours to submit the required documentation to CMS for total annual burden of 9,568 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 668 MA contracts 15 hours to submit the required documentation to CMS for total annual burden of 10,020 hours.**

§423.336 Risk sharing 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 85 Part D only contract 77 PACE contracts, and 668 MA contract 10 hours per month to submit the required documentation to CMS for total annual burden of 104,640 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 85 Part D Only contracts, 77 PACE contracts and 668 MA contract 10 hours to submit the required documentation to CMS for total annual burden of 8,720 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 85 Part D Only contracts, 77 PACE contracts and 668 MA contracts 10 hours to submit the required documentation to CMS for total annual burden of 8,720 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 and is included under the Application PRA package OMB #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 OMB #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 OMB # 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 OMB# 0938-0936.**

§423.505 Contract provisions

(d)The Part D sponsor agrees must maintain for 10 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 852 respondents 52 hours to maintain the required documentation on an annual basis, for total annual burden of 44,304.** The estimated annual cost is $1,387,158. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (44,304).

(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 852 respondents 8 hours to submit the required documentation to CMS for total annual burden of 6,816 hours.**

The estimated annual cost is $213,409. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (6,816).

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 an 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. **Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).**

§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. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

§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. Since this requirement affects less than 10, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).

§423.514 Validation of Part D reporting requirements.

The burden estimate for the validation of Part D 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 and the information must satisfy the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for each of the 424 Part D plan sponsors to disclose the necessary information to enrollees. **We estimate that it will require each of the 424 Part D plan sponsors 8 hours on an annual basis to disclose the information for a total annual burden of 3,392 hours.**

§423.564 Grievance procedures.

(e) A 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 an 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 receives the oral or written grievance. We estimate that 424 Part D plan sponsors will provide notification of 55,334 grievance decisions. The Part D plan must provide written notification of the decision if the grievance was submitted in writing, if the enrollee requests a written response, or if the grievance relates to a quality of care issue. **We estimate that the plan sponsor will have to provide written notification to enrollees in 13,200 grievances and oral notification in 118,800 grievances. We estimate it will take 30 minutes (0.5 hours) to provide written notification for a total annual burden of 6,600 hours. We estimate it will take 15 minutes (0.25 hours) to provide oral notification to enrollees for a total annual burden of 29,700 hours.**

(g) The Part D plan 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 notified the enrollee of the disposition.

The burden associated with this requirement is the time and effort necessary for Part D plans to maintain the required documentation outlined in this section. **We estimate that on an annual basis it will take 424 Part D plans 52 hours to maintain the required documentation on an annual basis, for a total annual burden of 22,048 hours.**

§423.568 Standard timeframe and notice requirements for coverage determinations.

(a)(3) A Part D plan sponsor must accept requests for benefits orally or in writing and must establish and maintain a method of documenting all oral requests for standard coverage

determinations and retain the documentation in the case file.

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to document oral requests and retain the documentation in the case file. We estimate that Part D plan sponsors will receive about 3,675,000 standard coverage determination requests annually and, of that number, 1,837,500 will be oral requests. We estimate that it will take a Part D plan sponsor 3 minutes (0.05 hours) to document and retain the required documentation in the case file. **Thus, we estimate that it will take 424 Part D plan sponsors a total of 91,875 hours to perform this function on an annual basis.**

(b), (c), (d) and (f) When a party makes a request for a drug benefit, a Part D plan sponsor must notify the enrollee in writing of favorable and unfavorable decisions. Enrollees (and the enrollee's prescriber, as appropriate) must be notified of a coverage decision 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 or other prescriber's supporting statement. For payment requests, the plan sponsor must notify the enrollee of its decision and make any applicable payment no later than 14 calendar days after receiving the request.

The burden associated with this requirement is the time and effort necessary for the 424 Part D plan sponsors to provide written notice to the enrollee. **We estimate it will take a plan sponsor 15 minutes (0.25 hours) to issue a written denial notice in 1,139,250 cases for a total estimate of 284,813 hours. We estimate it will take a plan sponsor 15 minutes (0.25 hours) to issue a written notice for 2,535,750 favorable decisions for a total estimate of 633,938 hours.**

§423.570 Expediting certain coverage determinations.

(c)(2) A 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 plans to maintain the required documentation outlined in this section. We estimate that on an annual basis Part D plan sponsors will receive 1,225,000 expedited coverage determination requests, of which 1,163,750 will be received orally. We estimate it will take 3 minutes (0.05 hours) for a plan sponsor to document an oral request for an expedited coverage determination. **Thus, it will take 424 Part D plan sponsors 58,188 hours to perform this function on an annual basis.**

(d) If a Part D plan 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 424 Part D plan sponsors to disclose the necessary information to an enrollee. **We estimate that 12,250 expedited requests will be transferred to the standard adjudication process. We estimate that it will take plan sponsors 15 minutes (0.25 hours) to provide this notice, for a total annual burden of 3,063 hours.**

§423.572 Timeframes and notice requirements for expedited coverage determinations.

(a) and (c) A Part D plan sponsor must notify the enrollee (and the prescribing physician or

other prescriber 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 or other prescriber's supporting statement. Plan sponsors must notify enrollees in writing of favorable and unfavorable expedited coverage determinations.

The burden associated with this requirement is the time and effort necessary for each of the 424 Part D plan sponsors to disclose the necessary information to an enrollee and prescribing physician or other prescriber involved. **We estimate it will take 15 minutes (0.25 hours) to provide notice of 1,212,750 expedited coverage determination decisions for a total estimated annual burden of 303,188 hours.**

§423.578 Exceptions process.

(a) and (b) An enrollee, the enrollee's representative, or the enrollee's prescribing physician or other prescriber (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 an exception request. **We estimate that that 3,185,000 exception requests will be received by 424 Part D plan sponsors. We further estimate it will take an individual an average of 15 minutes (0.25 hours) to provide the request for a total annual burden of 796,250 hours.**

Exception requests must be supporting by a statement from the enrollee's prescriber and if the supporting statement is provided orally, a Part D plan sponsor may require a written follow-up. The burden associated with this requirement is the time and effort necessary for a prescribing physician or other prescriber to submit the written supporting statement or other medical documentation to the Part D plan sponsor. **We estimate 2,388,750 requests will require written documentation and that it will take the physician or other prescriber 15 minutes (0.25 hours) to provide the supporting documentation. Therefore, we estimate a total annual burden of 597,188 hours.**

§423.580 Right to a redetermination.

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

§423.582 Request for a standard redetermination.

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

§423.584 Expediting certain redeterminations.

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

§423.590 Timeframes and responsibility for making redeterminations.

The information collection requirements referenced in this section are exempt from the PRA in accordance with 5 CFR 1320.4(a)(2) which excludes collection activities during the conduct of administrative actions, such as redeterminations, reconsiderations, and/or appeals.

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.**

§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 852 respondents 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 852 respondents to maintain the information for tracking purposes. **Therefore, we estimate a total annual burden of 66,456 hours to comply with these requirements.** The estimated annual cost is $2,080,737. This is based upon the national median hourly rate of $31.31 for a business operations staff person multiplied by the number of burden hours (66,456).

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 fewer than 10 fallback entities will submit a bid every three years. **Since this requirement affects less than 10 entities, it is exempt from the PRA in accordance with 5 CFR 1320.3(c).**

(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, 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 entities, 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 prepare and 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 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. **The Retiree Drug Subsidy program application for plan sponsors, the instructions for completing the application, and all corresponding burden estimates and estimates of participation, are included under the following separate information collection instrument: OMB# 0938-0957, Retiree Drug Subsidy (RDS) Application and Instructions.**

§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 may 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 with a final reconciliation within 15 months after the end of the plan year. For final reconciliation purposes, sponsors must submit actual cost data for the categories of costs in the preceding sentence (they may not submit estimated premium amounts), as well as actual, as opposed to estimated, rebates and other price concessions, 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 and burden estimates, estimates of participation, 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 1 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 (60 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 6,120 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 reflected in OMB #0938-0502.

(d) The subpart also requires States to submit an electronic file, in a manner specified by

the Secretary, identifying each full benefit dual eligible beneficiary 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 $213,710. This estimate is based upon the hourly rate at the GS-11/step 6 $34.92 multiplied by the number of burden hours (6,120).

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.

14. Cost to the Federal Government

We estimate that on an annual basis 200 individuals will be required to pay arrearages for Part D-IRMAA to CMS in order to be reinstated. We estimate that it will take a CMS staff person 5 minutes (0.083) to compile the arrearage information and 1 minute (0.017 hours) to assemble and disseminate the notice for each Part D-IRMAA favorable determination. 200 notices x 0.1 hours (6 minutes) = 20 hours. The estimated annual cost is $698. This is based upon the hourly rate at the GS-11/step 6 $34.92 multiplied by the number of burden hours (20).

15. Changes to Burden

This is a revision of an approved collection. The differences in the burden estimate are due to factors such as decreases in the number of Part D contracts and in the number of new Part D enrollees. Our additional experience with the program as well as data reported by the Part D sponsors have also enabled us to refine our previous estimates, resulting in a number of significant changes to the burden.

More specifically, in §§ 423.120, 423.128, 423.153, and 423.505, the decreased burden is due to decreases in the number of Part D sponsors. Other changes were based on additional program experience that permitted a refinement of our previous estimates of burden hours or number of responses. In §§ 423.32, 423.44, 423.56, 423.564, 423.568, 423.570, 423.572, and 423.578, the decreased burden occurred because of decreases in the number of people newly enrolling in Part D and in the number of Part D sponsors. Other changes to burden

requirements were due to the correction of errors in previous calculations, new regulatory requirements associated with Part D IRMAA and additional experience with the program that permitted a refinement of the estimates. Finally, in §§ 423.329, 423.336, 423.343, and 423.892 the increase in burden occurred because of adjustments made to the number of sponsors included in the estimates.

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.

B. Collections of Information Employing Statistical Methods

Not applicable.