Supporting Statement Part A
Comprehensive Addiction and Recovery Act of 2016 (CARA) /
Medicare Prescription Drug Benefit Program
CMS-10141, OMB 0938-0964

BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) published a final rule to establish the Medicare Prescription Drug Benefit 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 and continue to support administration of the program. The 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). As specified in the MMA, the prescription drug benefit program became available to beneficiaries beginning on January 1, 2006.

Revisions: Drug utilization management; Drug management programs

The Comprehensive Addiction and Recovery Act of 2016 (CARA), enacted into law on July 22, 2016, amended the Social Security Act and included new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Pursuant to section 704(g)(3) of CARA and revised section 1860D-4(c), CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries." Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies).

CMS-4182-F; RIN 0938-AT08 (final rule) implements the CARA Part D drug management program provisions by integrating them with the existing Part D Opioid Drug Utilization Review (DUR) Policy and Overutilization Monitoring System (OMS) activities ("current policy"). This integration means that Part D sponsors that implement a drug management program could limit an at-risk beneficiary's access to coverage of frequently abused drugs through a point-of-sale (POS) edit and/or by requiring the beneficiary to obtain the drugs from a selected pharmacy(ies) and/or prescriber(s) after case management and notice to the beneficiary, if the beneficiary meets clinical guidelines that factor in that the beneficiary has taken the drugs over a sustained time period and obtained them from multiple prescribers and pharmacies. This final rule also implements a limitation on the use of the special enrollment period (SEP) for certain dually- or other low income subsidy (LIS)-eligible beneficiaries who are identified as potential or confirmed to be at-risk beneficiaries.

One purpose of this 2018 package iteration is to request OMB approval for the following new drug management program requirements/burden as set out under § 423.153(f):

- Part D plan sponsors will be required to notify certainbeneficiaries about their plan's drug management program.
- Part D plan sponsors will be required to upload these new notice templates into their internal claims systems.

Revisions: Access to Covered Part D Drugs; Preclusion List

In order to protect the Medicare Part D beneficiaries and the integrity of the program, while minimizing disruption to beneficiaries' access to needed Part D medications and the administrative burden on the provider community, CMS finalized the elimination of the Part D enrollment requirement in CMS-4182-F (RIN 0938-AT08) (final rule). Instead, CMS will compile a "Preclusion List", which will consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber, to the extent applicable, if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or will have led, to the revocation is detrimental to the best interests of the Medicare program. Under the final rule, CMS will make the Preclusion List available to Part D sponsors and a Part D sponsor must reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List.

Another purpose of this 2018 package iteration is to request OMB approval for the following final requirements/burden as set out under § 423.120(c)(6):

- Part D sponsor's system programming of the Preclusion List,
- Creation of model e-notices to be issued to the Medicare beneficiaries and prescribers when a prescriber is identified on the Preclusion List, and
- Preparation and issuance of the model notices to Medicare beneficiaries and prescribers.

A. JUSTIFICATION

1. Need and Legal Basis

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 102, 103, 104 and 109 to the Social Security Act (the Act) establishing the Medicare prescription drug benefit (Part D) program.

The existing information requirements are mandated by regulations at §§ 422.504(o) and 423.505(p) which were finalized on February 12, 2015. These provisions respectively require MA organizations and Part D sponsors to develop business continuity plans with the goal of better ensuring beneficiary access to health care services and Part D drugs during and after interruptions to regular business operations. (80 FR 7912). However, when we originally proposed these regulations on January 10, 2014, we did not include these proposed regulations in the Collection of Information Requirements section, which meant there was no 60 day notice to solicit public comment. (79 FR 1918). To correct this oversight we published separate Federal Register notices

(April 10, 2015, 80 FR 19323 and June 19, 2015, 80 FR 35362) which solicited public comment for 60- and 30-days, respectively. No comments were received in response to these solicitations.

Revisions: Drug utilization management; drug management programs

CARAincluded new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Pursuant to section 704(g)(3) of CARA and revised section 1860D-4(c), CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries."

Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies). The final rule stipulates that Part D plan sponsors are required to notify certain beneficiaries about their plan's drug management program. Specifically, Part D sponsor must send potential at-risk beneficiaries a written notice confirming whether the sponsors have determined that the beneficiaries are at-risk or not.

Revisions: Access to Covered Part D Drugs; Preclusion List

The final rule creates Preclusion List requirements at § 423.120(c)(5) and (c)(6). The provisions require CMS to compile a "Preclusion List", which will consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber, to the extent applicable, if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or will have led, to the revocation is detrimental to the best interests of the Medicare program.

CMS will make the Preclusion List available to Part D sponsors and a Part D sponsor must reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an prescriber on the Preclusion List. Before doing so, Part D sponsors must provide a written notice to the beneficiary about the prescriber's presence on the Preclusion List and also take reasonable efforts to notify to the prescriber regarding a beneficiary who received a notice. The burden associated with these provisions will be the time and effort necessary for Part D systems to be programmed and for model notices to be created, generated, and disseminated. CMS will create and disseminate model notices to the prescribers to notify them of their existence on the Preclusion List, while the Part D sponsors will create and disseminate model notices to the Medicare beneficiaries to notify them that the pharmacy claim is being rejected or denied due to the prescriber's existence on the Preclusion List.

2. Information Users

The Centers for Medicare and Medicaid Services (CMS) published a final rule to establish the Medicare Prescription Drug Benefit 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 and continue to support administration of the program. The 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). As specified in the MMA, the prescription drug benefit program became available to beneficiaries beginning on January 1, 2006.
Part D plans and, to the extent applicable, MA organizations will use the information discussed below to comply with the eligibility and other requirements associated with their participation in Part D. CMS will use this information from plan sponsors and States to approve contract applications, monitor compliance with contract requirements, make proper payment to plans, and ensure that correct information is disclosed to potential and current enrollees. The information collection will allow CMS to ensure sponsors have plans in place to restore business operations following a disruption of regular operations. Medicare beneficiaries will use the information provided by the Part D sponsors to make decisions regarding Part D enrollment as well as grievance and appeal requests.

Revisions: Drug utilization management; drug management programs

CARA included new authority for Medicare Part D drug management programs, effective on or after January 1, 2019. Pursuant to section 704(g)(3) of CARA and revised section 1860D-4(c), CMS must establish through notice and comment rulemaking a framework under which Part D plan sponsors may establish a drug management program for beneficiaries at risk for prescription drug abuse or misuse, or "at-risk beneficiaries."

Under such a Part D drug management program, sponsors may limit at-risk beneficiaries' access to coverage of controlled substances that CMS determines are "frequently abused drugs" to a selected prescriber(s) and/or network pharmacy(ies). The final rule stipulates that Part D plan sponsors are required to notify certain beneficiaries about their plan's drug management program. Specifically, Part D sponsor must send potential at-risk beneficiaries a written notice confirming whether the sponsors have determined that the beneficiaries are at-risk or not.

The information users are certain Part D beneficiaries who receive the notifications from the Part D plan sponsors.
Revisions: Access to Covered Part D Drugs; Preclusion List

The final rule creates Preclusion List requirements at § 423.120(c)(5) and (c)(6). The provisions require CMS to compile a "Preclusion List", which will consist of certain prescribers who are currently revoked from the Medicare program under § 424.535 and are under an active reenrollment bar, or have engaged in behavior for which CMS could have revoked the prescriber, to the extent applicable, if he or she had been enrolled in Medicare, and CMS determines that the underlying conduct that led, or will have led, to the revocation is detrimental to the best interests of the Medicare program.

CMS will make the Preclusion List available to Part D sponsors The Part D sponsors will perform system programming to maintain the Preclusion List in order to reject a pharmacy claim (or deny a beneficiary request for reimbursement) for a Part D drug that is prescribed by an individual on the Preclusion List. Before doing so, Part D sponsors must provide a written notice to the beneficiary about the prescriber's presence on the Preclusion List and also take reasonable efforts to notify to

the prescriber regarding a beneficiary who received a notice. The burden associated with these provisions will be the time and effort necessary for Part D systems to be programmed and for model notices to be created, generated, and disseminated.

CMS will create and disseminate model notices to the prescribers to notify them of their existence on the Preclusion List, while the Part D sponsors will create and disseminate model notices to the Medicare beneficiaries to notify them that the pharmacy claim is being rejected or denied due to the prescriber's existence on the Preclusion List.

The information users are certain Part D beneficiaries and their prescribers who receive the notifications from the Part D plan sponsors.

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.

Revisions: Drug utilization management; drug management programs

Part D plan sponsors are required to upload the new beneficiary model notices into their internal systems so that they can provide the written notices to the applicable beneficiaries as required. Also, Part D plan sponsors must submit beneficiary notice and limitation information in CMS' Medicare Advantage Prescription Drug (MARx) System. The submission is 100% electronic. The beneficiary notices will be sent through the mail.

Revisions: Access to Covered Part D Drugs; Preclusion List
CMS will use email to notify providers in advance of their inclusion on the Preclusion List. CMS will make the Preclusion List available to Part D plan sponsors in electronic, downloadable format through the CMS' Enterprise Identity Data Management (EIDM) system. Part D sponsors will program their claim adjudication systems for beneficiary notices to be created, generated, and disseminated about prescribers on the Preclusion List.
Beneficiaries will receive the notices through the mail.

4. Duplication of Similar Information

This collection does not contain duplication of similar information.

5. Small Businesses

Some Part D sponsors and MA 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 on the least frequent basis necessary to support CMS' administration of the Part D and MA programs and plan sponsor's provision of benefits under their contracts with CMS. With less frequent collection, CMS would not have access to the data necessary to administer these programs and plan sponsors.

For example, under the information collection on business continuity plans, existing plan sponsors are required to annually test their plan and update these documents as needed. New plan sponsors without existing business continuity plans must develop and implement such plans. Business continuity plans ensure that plan sponsors are able to restore business operations after disruptions caused by events such as natural or man-made disasters, systems failures and emergencies. In another example information collected from beneficiaries is collected when an enrollment application is filed and when a coverage determination is requested. Other information, such as other payers reimbursing Part D costs on the enrollee's behalf, is collected from beneficiaries only annually. Information from Part D sponsors related, for example, to drug utilization management or dissemination of plan information, is an annually requirement; however, although bid information from sponsors is an annual collection, cost information is collected monthly. Information collected from the states pertaining to low-income subsidy determinations and redeterminations is collected monthly.

Conducting testing of business continuity plans less frequently than annually increases the risks associated with a service disruption to beneficiary access to care and coverage. Some other consequences of less frequent collection 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

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

The November 28, 2017 (82 FR 56336), proposed rule (CMS-4182-P, RIN 0938-AT08) served as the 60-day Federal Register notice. We did not receive any comments pertaining to our proposed requirements. Consequently, we are finalizing them as proposed.

The final rule published on April 16, 2018 (83 FR 16440) and is effective on June 15, 2018.

9. Payments/Gifts To Respondents

There are no payments/gifts to respondents.

10. Confidentiality

CMS recognizes the potential confidential or proprietary nature of the information related to the information collection on business continuity plans. Plans are not required as a matter of course to submit these plans to CMS or to make such plans publicly available. If CMS requests the documents, we do not intend to voluntarily disclose then to any parties outside the government. Although the documents may be subject to release under the Freedom of Information Act (FOIA) plan sponsors may seek to protect their information from disclosure by claiming FOIA exemption 4 and taking the appropriate steps, including labeling the information in questions as “confidential” or “proprietary.”

The information collected from organizations for the purposes of disclosing to the potential enrollees their health care coverage choices is public information. The information 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 Parts 417, 422, and 423 including all Federal and State laws regarding confidentiality and disclosure.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimate (Total Hours & Wages)

This section consists of the following subsections:
Wages
Requirements and Annual Burden Estimates

12.1 ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p)
(No Changes)
12.2 ICRs Regarding Medicare Prescription Drug Benefit Program (Beneficiaries)
(No Changes)
12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans)
(Revised)
12.4 ICRs Regarding State Eligibility Determinations (§423.904(b)) and Reporting (§423.910(d))
(No Changes)
12.5 ICRs Regarding the Part D Sponsor's System Programming
(New ICR)
12.6 ICRs Regarding the Creation of Model Notices to the Medicare Beneficiaries and Prescribers
(New ICR)
12.7 ICRs Regarding the Preparation and Issuance of the Model Notices to the Medicare Beneficiaries and Prescribers
(New ICR)

Summary of Requirements and Annual Burden Estimates
Information Collection Instruments, Instructions and Guidance Documents
ICRs Exempt from the Requirements of the Paperwork Reduction Act
ICRs Approved Under Other OMB Control Numbers

- *Wages*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

BLS Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	35.14	35.14	70.28
Computer Programmer	15-1131	42.08	42.08	84.16
Insurance Claim and Policy	43-9041	19.76	19.76	39.52

Processing Clerk				
Software Developers and Programmers	15-1130	49.27	49.27	98.54

- *Requirements and Annual Burden Estimates*

The following information collection requests consist of three existing Information Collection Requests (ICRs) that remain unchanged (see sections 12.1, 12.2, and 12.4) along with three new ICRs (see sections 12.5, 12.6, and 12.7). Revisions to section 12.3 is limited to CARA provisions under section 12.3.10. Burden has been adjusted (see section 15) in sections 12.3.1, 12.3.3, 12.3.4, 12.3.6, 12.3.7, 12.3.8, 12.3.9, 12.3.10, 12.3.13, 12.3.15, 12.3.17, and 12.3.23.

The burden associated with the new information collection provisions (sections 12.5, 12.6, and 12.7) and the revised provision (12.3.10) are finalized under CMS-4182-F (RIN 0938-AT08).

12.1 ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p) (NO CHANGES)

12.1.1 Contract provisions (§§ 422.504 and 423.505)

Sections 422.504(o) and 423.505(p) require, respectively, MA organizations and Part D sponsors to develop, maintain, and implement business continuity plans that identify potential business disruptions and develop ways to maintain functions or restore them as soon possible thereafter. We believe many entities already have developed and are maintaining plans that meet these requirements for two reasons - 1) creating business continuity plans is a well-established practice across most industries; and 2) CMS finalized a regulation (80 FR 7912) that created flexibility for industry practices related to business continuity. Accordingly, the burden associated with the requirement is the time and effort necessary for Part D sponsors and MA organizations without plans to develop and maintain business continuity plans and the time and effort for entities that have existing business continuity plans that do not meet all the requirements to revise them. For the first year, we estimate 28 entities do not have the plans in place and it will take 240 hours each to fulfill the business continuity requirements, for a total burden of **6,720 hours** (28 plans x 240 hrs). We also estimate that there are 57 entities with existing plans that need to be updated and it will take **120 hours** to revise their business continuity plans in the first year, for a total burden of **6,840 hours** (6,720 hrs + 120 hrs) at a cost of $ 480,715.20 (6,840 hr x $70.28) for a business operations specialist.

In subsequent years, we estimate there will be 9 new Part D sponsors and MA organizations that do not already have a business continuity plan based on our experience that most entities that create new plans each year are under parent organizations that already have business continuity plans in place. We estimate a burden of 240 hours for each of these 9 entities. We also estimate that 5 entities with existing plans will either experience a problem or for some other reason update their plan and it will take each plan 40 hours for these revisions. For each subsequent year, we estimate 9 entities will not have the plans in place and it will take 240 hours each to fulfill the

business continuity requirements, for a total burden of **2,160 hours** (240 hrs x 9 plans). We also estimate for each subsequent year 5 entities with existing plans will need to update their business continuity plans and it will take 40 hours for each plan to make these revisions, for a total burden of **200 hours** (40 hrs x 5 plans) at a cost of $ 14,056 (200 hr x $70.28) for a business operations specialist.

Business Continuity Plans: Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.505(p) combined with 422.504(o)	Private sector (Contracts)	28	240	1	28	6,720
		57	120	1	57	6,840
		9	240	1	9	2,160
		5	40	1	5	200
Subtotal		**99**	**Varies**	**1**	**99**	**15,920**

12.2 ICRs Regarding Medicare Prescription Drug Benefit Program (Benes) (NO CHANGE)

The following ICRs are related to the enrollment process and creditable coverage.

12.2.1 Enrollment process (§ 423.32)

(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 submitting an enrollment request to the Part D plan through one of the mechanisms CMS determines are appropriate.

The burden associated with this requirement is the time and effort necessary for an individual to submit the enrollment request to a Part D plan sponsor. We estimate that it will take 30 minutes (0.5 hours) to complete and submit the request 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 request 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 the Fall of 2017, about 1.9 million individuals newly enrolled in or switched stand-alone Medicare prescription drug plans (PDPs) during the annual coordinated election period; these enrollments took effect on January 1 of 2018. New PDP enrollments (not counting those with a January 1 effective date) average approximately 186.000 per month. Therefore, it is estimated that a total of 3.954 million individuals may newly enroll in or change their PDP annually. The total burden is calculated to be **1,975,000 hours** (3,954,000 million enrollments x 0.5 hours).

(b) Enrollment form or CMS-approved mechanism. The enrollment request 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 enrolled or enrolling in a Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement is a 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** (2,600,000 million beneficiaries x .017 hrs).

12.2.2 Enrollment of full-benefit dual eligible individuals (§ 423.34)

Section 423.34(e) states that a full-benefit dual eligible beneficiary may decline automatic 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 will 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 will need to contact the plan only once. There are, on average, approximately 130,000 individuals who choose their own plan instead of the automatic enrollment each year so we estimate that it takes full dual beneficiaries 32,500 hours each year to decline the automatic enrollment or enroll in a different plan (causing a disenrollment). We further estimate the same amount of time for plans to receive and process these enrollments/disenrollments. The total number of hours is **32,500 hours** for the full dual beneficiaries (130,000 beneficiaries x .25 hrs).

12.2.3 Enrollment periods (§ 423.38)

In paragraph (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 expect that fewer than 10 individuals, if any, will avail themselves of this option. Generally, in those instances where CMS has found that an MA 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.

12.2.4 Procedures to document creditable status of prescription drug coverage (§ 423.56)

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 penalty 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. Based on recent experience (i.e., 2012 – 2014, we estimate that on an annual basis it will take 100 individuals 15 minutes (0.25 hours) to apply to CMS, for a total of **25 hours** (100 beneficiaries x .25 hrs).

12.2.5 Exceptions process (§ 423.578)

In paragraphs (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** (3,185,000 requests x .25 hrs).

12.2.6 Burden Summary

Medicare Prescription Drug Benefit Program (Benes): Burden Summary (Subtotal)

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	3,954,000	0.5	1	3,954,000	1,975,000
423.32(b)	Individual	2,600,000	0.017 (1 min)	1	2,600,000	44,200
423.34(e)	Individual	130,000	0.25	1	130,000	32,500
423.56(f)	Individual	100	0.25	1	100	25
423.578(a) and (b)	Individual	3,185,000	0.25	1	3,185,000	796,250
Subtotal		**9,869,100**	**-varies**	**1**	**9,869,100**	**2,847,975**

12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans)
(Revisions to section 12.3 is limited to CARA provisions under section 12.3.10. Burden has been adjusted and corrected (see section 15) in sections 12.3.1, 12.3.3, 12.3.4, 12.3.6, 12.3.7, 12.3.8, 12.3.9, 12.3.10, 12.3.13, 12.3.15, 12.3.17, and 12.3.23)

12.3.1 Enrollment process (§ 423.32)

(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 provide 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 he or she will be covered under the plan. There are approximately 757 Part D plan sponsors in 2018 . Each Part D plan creates the acceptance and denial 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. 757 plan sponsors x (3 hours x 2 notices) = **4,542**. We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) for a business operations specialist to assemble and disseminate the proper notice for each of the enrollment requests received annually. 3.954 million requests x 0.017 hours (1 minute each) = **67,218 hours**. The total number of hours is **71,760** (4,542 + 67,218) or 92.43 hours per sponsor annually. The estimated annual cost is $5,043,293 ($70.28 / hr x 71,760 hr).

12.3.2 Enrollment of full-benefit dual eligible individuals (§ 423.34)

As noted above, section 423.34(e) states that a full-benefit dual eligible beneficiary may decline automatic 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 automatic enrollment or to actively enroll in a new, and for plans to process the enrollments and disenrollments. We estimate it will take an individual about 15 minutes (0.25 hours) to, either contact the plan to decline the automatic enrollment or contact a different 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 will need to contact the plan only once. There are on average approximately 130,000 individuals who choose their own plan instead of the automatic enrollment each year so we estimate that it takes full dual beneficiaries 32,500 hours a year to decline the automatic enrollment or enroll in a different plan (causing a disenrollment) each year. We further estimate the same amount of time for plans to receive and process these declinations/enrollments. The total burden is **32,500 hours** for a business operations specialist for the 757 Part D plan sponsors. The estimated annual cost is $2,284,100 ($70.28 /hr x 32,500 hr).

12.3.3 Disenrollment process (§ 423.36)

Section (b) requires the Part D plan sponsor to submit a disenrollment transaction 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 provide an individual a notice of disenrollment, whether it is the result of the individual leaving the Part D program or switching plans during a valid enrollment period. Based on disenrollment data for January through August 2017, we estimate that on an annual basis it will require a total of 1,903,752 notices, affecting each Part D plan sponsors to some degree, as described below. There are approximately 757 Part D plan sponsors in 2017. Each Part D plan creates the disenrollment 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 sponsor approximately 1 hour for a business operations specialist to produce the notice. 757 plan sponsors x 1 hour = **757** hours. We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) for a business operations specialist to assemble and disseminate the notice for each disenrollment. 1,903,752 notices x 0.017 hours (1 minute each) = **32,364** hours. The total number of hours is **33,121 hours** (757 + 32,364) or 42.8 hours per sponsor annually. The estimated annual cost is $2,327,744 ($70.28 /hr x 33,121 hr).

12.3.4 Involuntary disenrollment by the Part D plan (§ 423.44)

If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i) or (b)(2)(iv) of § 423.44, the Part D plan sponsor must give the individual timely notice of the disenrollment with an explanation of why the Part D plan is seeking to disenroll the individual. Notices for these

reasons 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 plan 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 provide an individual the notice of disenrollment. There are approximately 757 Part D plan sponsors in 2017. Each Part D plan creates the disenrollment 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. 757 plan sponsors x 1 hour = **757 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) for a business operations specialist to assemble and disseminate the notice for each disenrollment. Based on disenrollment data for January through June 2017, we estimate that on an annual basis 496,344 individuals will be disenrolled for failure to pay premiums. 496,344 notices x 0.1 hours (6 minutes each) = **49,634 hours**. The total number of hours is **50,391** (757 + 49,634) or 63.6 hours per sponsor annually. The estimated annual cost is $3,544,010 ($70.28 /hr x 50,427 hr).

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 757 Part D plan sponsors in 2017. Each Part D plan creates the disenrollment 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. 757 plan sponsors x 1 hour = **757 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. Based on data from January 1 through September 23, 2017, we estimate that on an annual basis 1,100 individuals will be disenrolled for failure to pay Part D-IRMAA. 1,100 notices x 0.017 hours = **18.7 hours**. The total number of hours is **775.7** (757 + 18.7) or 1.02 hours per sponsor annually. The estimated annual cost is $54,516($70.28 /hr x 775.7 hr).

An individual who is disenrolled for non-payment of plan premiums or non-payment Part D-IRMAA may be reinstated by the Part D sponsor or by CMS, respectively, if the individual shows good cause for not paying premiums timely. In this process, the plan or CMS determines if good

cause is met based on the individual's request for review and his or her 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 by the plan sponsor of the plan premium amount owed for reinstatement. 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 provide an individual the notice of the owed plan premium amount required for reinstatement. There are approximately 757 Part D plan sponsors in 2017. Each Part D plan creates the notice of the plan premium amount owed, 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. 757 plan sponsors x 1 hour = **757 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) for a business operations specialist to assemble and disseminate the notice for each favorable determination. We estimate that on an annual basis 17,772 individuals will request and receive favorable good cause determinations. 17,772 notices x 0.1 hours (6 minutes) = **1,777 hours**. The total number of hours is **2,534** (757 + 1,777) or 3.24 hours per sponsor annually. The estimated annual cost is $ 178,990 ($70.28 /hr x 2,534 hr).

A Part D plan may disenroll an individual whose behavior is disruptive, only after it meets the requirements described in guidance 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 guidance. 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 § 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. 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 §§ §§ 423.507 and 423.510.

12.3.5 Late enrollment penalty (§ 423.46)

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. Individuals enrolling in Part D with 63 days or more without creditable coverage will be assessed a Part D late enrollment penalty.

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 757 Part D plan sponsors in 2017. To comply with this requirement, Part D sponsors will 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 a total of 3.954 million individuals may newly enroll in or change their Part D plans annually and, as such, approximately 3,954 million new Part D enrollees will need to provide this information on an annual basis. Therefore the total annual burden associated with this requirement will be 3.954 million new enrollees x 0.25 hours (15 minutes) = **988,500 hours**. The estimated annual cost is $69,471,780 ($70.28 /hr x 988,500 hr)..

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 will expend 5 minutes (0.083 hours) per new Part D enrollee. We estimate that a total of 3.954 million individuals may newly enroll in or change their Part D plan annually. We estimate the total annual burden associated with this requirement will be **328,182 hours** for all new Part D enrollees. The estimated annual cost is $23,064,631 ($70.28 /hr x 328,182 hr).

12.3.6 Information about Part D (§ 423.48)

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 757 Part D sponsors 2 hours for a business operations specialist to submit the required documentation to CMS for a total annual burden of **1,514 hours**. The decrease in total annual burden from the previous estimate is due to the decreased number of respondents. The estimated annual cost is $106,403 ($70.28 /hr x 1,514 hr).

12.3.7 Requirements related to qualified prescription drug coverage (§ 423.104)

(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. Given the complexity of this reporting, we estimate the time and effort required will be similar to that associated with the payment-related reporting requirements. Therefore, we estimate that on an annual basis it will take each of the 757 respondents 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **7,570 hours**. The estimated annual cost is $532,019 ($70.28 /hr x 7,570 hr).

12.3.8 Access to covered Part D drugs (§ 423.120)

(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 757 respondents 2 hours each for a business operations specialist to capture and retain the required documentation on an annual basis for total annual burden of **1,514 hours**. The decrease in total annual burden from the previous estimate is due to the decreased number of respondents. The estimated annual cost is $106,403 ($70.28 /hr x 1,514 hr).

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, each of the 757 respondents 40 hours for a business operations specialist to disclose the required notice for a total annual burden of **30,280 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 $2,128,078 ($70.28 /hr x 30,280 hr).

Paragraph (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 will take an average of 5 minutes (0.083 hours) for a business operations specialist to prepare. Thus, we estimate the total burden to be **1,577,000 hours**. The estimated annual cost is $110,831,560 ($70.28 /hr x 1,577,000 hr).

(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 § 423.128.

12.3.9 Dissemination of plan information (§ 423.128)

(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 757 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 for a business operations specialist to disseminate the required materials to enrollees and eligible individuals for a total annual burden of **151,400 hours**. The decrease in total annual burden from the previously reported estimate is due to a correction in the number of respondents. The estimated annual cost is $10,640,392 ($70.28 /hr x 151,400 hr).

(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 757 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 for a business operations specialist to disseminate the required materials for total annual burden of **121,120 hours**. The decrease in total annual burden from the previously reported estimate is due to a correction in the number of respondents. The estimated annual cost is $8,512,314 ($70.28 /hr x 121,120 hr).

12.3.10 Drug Utilization Management, Quality Assurance, and Medication Therapy Management (MTM) (§ 423.153)
(Revised by adding finalized requirements/burden under paragraph (f))

(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 757 respondents 30 minutes (0.5 hours) for a business operations specialist to provide the required material to CMS for consideration for a total annual burden of **378.5 hours**. The decrease in total annual burden from the previously reported estimate is due to the decrease in the number of Part D plans. The estimated annual cost is $26,601 ($70.28 /hr x 378.5 hr).

(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 757 respondents 30 minutes (0.5 hours) for a business operations specialist to provide the required material to CMS for consideration for a total annual burden of **378.5 hours**. The decrease in total annual burden from the previously reported estimate is due to the decrease in the mean wage for a business operations specialist. The estimated annual cost is $26,601 ($70.28 /hr x 378.5 hr).

(f) Finalized § 423.153(f) will implement provisions of section 704 of CARA, which allows Part D plan sponsors to establish a drug management program that includes "lock-in" as a tool to manage an at-risk beneficiary's access to coverage of frequently abused drugs. Part D plan sponsors will be required to notify at-risk beneficiaries about their plan's drug management program. Part D plan sponsors are already expected to send a notice to some beneficiaries when the sponsor decides to implement a beneficiary-specific POS claim edit for opioids (the § 423.153 provision is approved by OMB under this control number). However, we believe that the approved information collection request only accounts for the notices that are currently sent to beneficiaries who have a POS edit put in place to monitor opioid access (which will count as the initial notice described in the preamble and defined in § 423.153(f)(4)) and will not capture the second notice that at-risk beneficiaries receive confirming their determination as such or the alternate second notice that potentially at-risk beneficiaries will receive to inform them that they were not determined to be at risk.

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. That results in approximately 923 edits annually. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber "lock-in" to OMS, to approximately 1,846 such limitations, we estimate 3,692 initial and, second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. Once the templates have been developed, we estimate it will take an average of 5 minutes (0.083 hours) at $39.22/hour for an insurance claim and policy processing clerk to prepare each notice. We

estimate an annual burden of **306 hours** (3,692 notices x 0.083 hour) at a cost of $12,093 (306 hrs x $39.52 /hr).

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations, based on plan year 2017 plan participation) will be subject to this requirement. We estimate that it will take on average 5 hours at $81.90/hour for a computer programmer to upload the notices into their claims systems. This will result in a total burden of **1,095 hours** (5 hour x 219 sponsors) at a cost of $92,155 (1,095 hr x $84.16 /hr).

In aggregate, the burden to upload and prepare these additional notices is **1,401 hours** (306 hours +1,095 hours) at a cost of $104,248 ($12,093 + $92,155).

12.3.11 Determination of payment (§ 423.329)

(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 70 stand-alone Part D plan contracts and 117 PACE contracts 52 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,724 hours**. The estimated annual cost is $683,402 ($70.28 /hr x 9,724 hr).

(b)(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 599 MA contracts 15 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **8,985 hours**. The estimated annual cost is $631,466 ($70.28 /hr x 8,985 hr).

12.3.12 Risk sharing arrangements (§ 423.336)

(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 percent 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 for a business operations specialist to submit the required

documentation to CMS for total annual burden of **100 hours**. The estimated annual cost is $ 7,028 ($70.28 /hr x 100 hr).

(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 each of the 757 Part D plan sponsors 10 hours per month for a business operations specialist to submit the required documentation to CMS for total annual burden of **90,840 hours**. The estimated annual cost is $6,384,235 ($70.28 /hr x 90,840 hr).

12.3.13 Retroactive adjustments and reconciliations (§ 423.343)

(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 each of the 757 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **7,570 hours**. The estimated annual cost is $532,020 ($70.28 /hr x 7,570 hr).

(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 each of the 757 Part D plan sponsors10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **7,570 hours**. The estimated annual cost is $532,020 ($ 70.28/hr x 7,570 hr).

12.3.14 Coordination of benefits with other providers of prescription drug coverage (§ 423.464)

(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).

12.3.15 Contract provisions (§ 423.505)

(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 757 respondents 52 hours for a business operations specialist to maintain the required documentation on an annual basis, for total annual burden of **39,364** hours. The estimated annual cost is $2,719,265 ($70.28 /hr x 39,364 hr).

(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 757 respondents 8 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **6,056 hours**. The estimated annual cost is $425,616 ($70.28 /hr x 6,056 hr).

12.3.16 Novation agreement requirements (§ 423.552)

(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.

12.3.17 General Provisions (§ 423.562)

(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 757 Part D plan sponsors to disclose the necessary information to enrollees. We estimate that it will require each of the 757 Part D plan sponsors 8 hours for a business operations specialist to disclose the information for a total annual burden of **6,056 hours**. The estimated annual cost is $425,615 ($70.28 /hr x 6,056 hr).

12.3.18 Grievance procedures (§ 423.564)

(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 757 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) for a business operations specialist to provide oral notification to enrollees for a total annual burden of **29,700 hours**. The total number of hours is **36,300** (6,600 + 29,700) annually. The estimated annual cost is $2,551,164 ($70.28 /hr x 36,300 hrs).

(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 757 Part D plan sponsors 52 hours for a business operations specialist to maintain the required documentation on an annual basis, for a total annual burden of **39,364 hours**. The estimated annual cost is $2,766,502 ($70.28 /hr x 39,364 hrs).

12.3.19 Standard timeframe and notice requirements for coverage determinations (§ 423.568)

(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) for a business operations specialist to document and retain the required documentation in the case file. Thus, we estimate that it will take 757 Part D plan sponsors a total of **91,875 hours** to perform this function on an annual basis. The estimated annual cost is $ 6,456,976 ($70.28 /hr x 91,875 hrs).

(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 757 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**.

The total number of hours is **918,751** (284,813 + 633,938) annually. The estimated annual cost is $64,569,820 ($70.28 /hr x 918,751 hrs).

12.3.20 Expediting certain coverage determinations (§ 423.570)

(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's business operations specialist to document an oral request for an expedited coverage determination. Thus, it will take 757 Part D plan sponsors **58,188 hours** to perform this function on an annual basis. The estimated annual cost is $4,089,453 ($70.28 / hr x 58,188 hrs).

(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 757 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) for a business operations specialist to provide this notice, for a total annual burden of **3,063 hours**. The estimated annual cost is $215,268 ($70.28 /hr x 3,063 hrs).

12.3.21 Timeframes and notice requirements for expedited coverage determinations (§ 423.572)

(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 757 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) for a business operations specialist to provide notice of 1,212,750 expedited coverage determination decisions for a total estimated annual burden of **303,188 hours**. The estimated annual cost is $21,303,133 ($70.28 /hr x 303,118 hrs).

12.3.22 Exceptions process (§ 423.578)

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**. The estimated annual cost is $54,481,461 ($91.23/hr x 597,188 hrs).

12.3.23 Administration of subsidy program (§ 423.800)

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 757 respondents approximately 52 hours for a business operations specialist to provide the information to CMS. We also estimate that it will take approximately 26 hours for each of the 757 respondents to maintain the information for tracking purposes. Therefore, we estimate a total annual burden of **59,046 hours** to comply with these requirements. The estimated annual cost is $4,149,753 ($70.28 /hr x 59,046 hr).

12.3.24 Change in Ownership (§ 423.892)

(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 1.0 hour for a business operations specialist to submit the required

notification to CMS, for a total of approximately **50 hours**. The estimated annual cost is $ 3,514 ($70.28 /hr x 50 hr).

12.3.25 Burden Summary

Medicare Prescription Drug Benefit Program (Plans): Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.32(d)	Private Sector	757	3	2	1,514	4,542
			0.017 (1 min)	4,986	3,954,000	67,218
423.34(e)	Private Sector	757	0.25	164	130,000	32,500
423.36(b)	Private Sector	757	1.017	32,401	1,903,752	33,121
423.44(b)	Private Sector	757	1	1	757	757
			0.1 (6 min)	626	496,344	49,634
			1	1	757	757
			0.017 (1 min)	1.4	1,100	18.7
			1	1	757	757
			0.1 (6 min)	22	17,772	1,777
423.46(b)	Private Sector	757	0.25	4,542	3,954,000	988,500
423.46(d)	Private Sector	757	0.083 (5 min)	4,542	3,954,000	328,182
423.48	Private Sector	757	2	1	757	1,514
423.104(g)	Private Sector	757	10	1	757	7,570
423.120(b)	Private Sector	757	2	1	757	1,514
			40	1	757	30,280
			0.083 (5 min)	1	19,000,000	1,577,000
423.128(a)	Private Sector	757	200	1	757	151,400
423.128(e)	Private Sector	757	160	1	757	121,120

423.153(b)	Private Sector	757	0.5	1	757	378.5
423.153(c)	Private Sector	757	0.5	1	757	378.5
423.153(f) NEW: CARA	Private Sector	219	0.083	17.4	3,692	307
423.153(f) NEW: CARA	Private Sector	219	5	1	219	1,095
423.329(b)	Private Sector	187	52	1	187	9,724
		599	15	1	599	8,985
423.336(a)	Private Sector	5	20	1	5	100
423.336(c)	Private Sector (Contracts)	757	10/month	12	9,516	95,160
423.343(c)	Private Sector (Contracts)	757	10	1	757	7,570
423.343(d)	Private Sector (Contracts)	757	10	1	757	7,570
423.505(d)	Private Sector	757	52	1	757	39,364
423.505(f)	Private Sector	757	8	1	757	6,056
423.562(a)	Private Sector	757	8	1	757	6,056
423.564(e)	Private Sector	757	0.5	16.6	13,200	6,600
			0.25	149.8	118,800	29,700
423.564(g)	Private Sector	757	52	1	757	39,364
423.568(a)(3)	Private Sector	757	0.05 (3 min)	2,317	1,837,500	91,875
423.568(b), (c), (d), and (f)	Private Sector	757	0.25	1436.6	1,139,250	284,813
			0.25	3,197.7	2,535,750	633,938
423.570(c)(2)	Private Sector	757	0.05 (3 min)	1,467.5	1,163,750	58,188
423.570(d)	Private Sector	757	0.25	15.4	12,250	3,063
423.572(a) and (c)	Private Sector	757	0.25	1,529.3	1,212,750	303,188
423.578(a) and (b)	Private Sector		0.25		2,388,750	597,188
423.800(b)	Private Sector	757	78	1	757	59,046

423.892(c)	Private Sector	50	1	1	50	50
Subtotal		**757**	--	--	**43,862,376**	**5,687,919**

12.4 ICRs Regarding State Eligibility Determinations (423.904(b)) and Reporting (423.910(d))
(No Changes)

12.4.1 Eligibility determinations for low-income subsidies (§ 423.904)

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 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**. Based on the experience to date, it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

12.4.2 Requirements (§ 423.910)

(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's business operations specialist 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 $430,114 ($70.28 /hr x 6,120 hr).

Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
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
Subtotal		**51**	**varies**	**varies**	**600,102**	**13,260**

12.5 ICRs Regarding the Part D Sponsor's System Programming (§ 423.120(c)(6)) (New ICR)

For this provision the burden will include the time and effort for Part D adjudication systems to be programmed for the model notices. We estimate that it will take sponsors and PBMs with Part D adjudication systems approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of § 423.120(c)(6). The sponsors and PBMs will need approximately six to twelve months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time Software Developers and Programmers at $98.54 /hr amounts to **93,600 hours** (3 workers x 1,040 hr x 30 sponsors/PBMs) at a cost of **$9,223,344** (93,600 hr x $ 98.54/hr) for 2019. This is a one-time burden. There will be no burden associated with 2020 and 2021.

Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.120(c)(6)	Private Sector	30	3,120	1	30	93,600
Subtotal		**30**	**3,120**	**1**	**30**	**93,600**

12.6 ICRs Regarding the Creation of Model Notices to the Medicare Beneficiaries and

Prescribers (§ 423.120(c)(6))
(New ICR)

The finalized provision will require that Part D sponsors provide written notice to the beneficiary and take reasonable efforts to furnish written notice to the prescriber.

For this provision the burden will include the time and effort for creating the model notices. We estimate that 212 parent organizations will need to create two model notices to notify beneficiaries and prescribers under finalized § 423.120(c)(6). We project that it will take each organization 3 hours at $70.28 /hr for a business operations specialist to create the two model notices. In aggregate, we estimate a one-time burden of **636 hours** (212 organizations x 3 hr) at a cost of **$44,698** (636 hr x $70.28 /hr)or $207.84 per organization ($44,698 /212 organizations) in 2019. There will be no burden associated with 2020 and 2021.

Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.120(c)(6)	Private Sector	212	3	1	212	636
Subtotal		**212**	**3**	**1**	**212**	**636**

12.7 ICRs Regarding the Preparation and Issuance of the Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6))
(New ICR)

For this provision we estimate that it will take an average of 5 minutes (0.083 hr) at $39.22/hour for an insurance claim and policy processing clerk to generate and disseminate the aforementioned notice. We estimate that an average of approximately 800 prescribers will be on the Preclusion List in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries will received prescriptions written by these prescribers and will therefore receive the notice referenced in § 423.120(c)(6). In aggregate, we estimate a burden of **6,640 hours** (0.083 hr/response x 80,000 responses) at a cost of **$262,413** (6,640 hr x $ 39.52/hr) or $1,242 per organization ($262,413 / 212 organizations) for an insurance claim and policy processing clerk to prepare and distribute the notices in 2019.

In 2020 and 2021, we estimate that roughly 150 prescribers will be added to the Preclusion List, though this will be largely offset by the same number of prescribers being updated to reflect a change in their preclusion status (for example, based on reenrollment after the expiration of a reenrollment bar) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of **1,245 hours** (15,000 beneficiaries x 0.083 hr) at a cost of **$49,202** (1,245 hr x $39.52 /hr) or $328.01 per prescriber ($49,202 /150 prescribers).

Burden Summary (Subtotal)

CFR Section	Respondent Type	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.120(c)(6)	Private Sector	800	0.083 (5 min)	varies	80,000	6,640
423.120(c)(6)	Private Sector	150	0.083 (5 min)	varies	15,000	1,245
Subtotal		**950**	0.083 (5 min)	**varies**	**95,000**	**7,885**

- Summary of Requirements and Annual Burden Estimates

Total Annual Burden Estimates

ICR Section	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
12.1. Business Continuity Plans (No Change)	99	Varies	1	99	15,920
12.3. Medicare Prescription Drug Benefit Program: Plans (Revised)	757	Varies	Varies	43,862,376	5,687,919
12.5. System Programming (New)	30	3,120	1	30	93,600
12.6. Creation of model notices (New)	212	3	1	212	636
12.7 Preparation and issuance of model notices (New)	950	0.083 (5 min)	varies	95,000	7,885
Subtotal (Private Sector)	*2,048*	*varies*	*varies*	*43,957,717*	*5,805,960*
12.2. Medicare Prescription Drug Benefit Program:Bene (No Change)	9,869,100	Varies	1	9,869,100	2,847,975
Subtotal (Individuals and Households)	*9,869,100*	*Varies*	*1*	*9,869,100*	*2,847,975*
12.4. State Eligibility Determinations (No Change)	51	Varies	varies	600,102	13,260
Subtotal (States)	*51*	*varies*	*varies*	*600,102*	*13,260*
TOTAL	**9,871,199**	**varies**	**varies**	**54,426,919**	**8,667,195**

The revisions associated with the Medicare Prescription Drug Benefit Program (PLAN) includes the Part D sponsor's system programming of the Preclusion List, creation of model notices to be issued to Medicare beneficiaries and prescribers when a prescriber is identified on the Preclusion List, and preparation and issuance of model notices to the Medicare beneficiaries and prescribers.

The system programming and creation of model notices is a one-time burden and is not considered an annual burden.

- Information Collection Instruments, Instructions And Guidance Documents

Attachments 1a and 1b - 2019 Compensation Certification

Attachments 2a and 2b – Structure Submission Form

Attachment 3 – Covered Agent Information Sheet

Attachment 4 - 2019 Compensation Structure for Writing Agents by Contract/PBP Number

Attachments 5a – 5c – Instructions

Attachments 6a – 6c – Drug Management Program Model Notices

Attachment 7a – Precluded Provider Model Notices

- ICRs Exempt from the Requirements of the PRA
(No Change)

Since we estimate fewer than ten annual respondents for the following information collections, the requirements and burden are exempt (see 5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

In § 423.168(c), an accreditation organization approved by CMS must provide to CMS in written form and on a monthly basis copies of accreditation surveys, notices of accreditation decisions, notice of all complaints, information about any remedial or adverse action taken, and notice of any finalized changes to accreditation standards, requirements or survey processes.

In § 423.171(a), a private, national accreditation organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

In § 423.507(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.

In § 423.508(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.

In § 423.509(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.

In § 423.510(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.

In § 423.551(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.

In § 423.552(a), Part D plan sponsors are required 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.

In § 423.859(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.

Section 423.863(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.

Section 423.863(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.

Section 423.871(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.

Section 423.907(a) 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) 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. We estimate that this requirement will affect 5 territories.

The following information collection requirements are associated with an administrative action (see 5 CFR 1320.4(a)(2) and (c)). Consequently, they are exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

In § 423.580, the requirements under Right to a Redetermination.

In § 423.582, the requirements under Request for a Standard Redetermination.

In § 423.584, the requirements under Expediting Certain Redeterminations.

In § 423.590, the requirements under Timeframes and Responsibility for Making redeterminations.

In Part 423, the requirements under subpart N (Medicare Contract Determinations and Appeals).

In § 423.756(a), 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.

We believe the burden associated with the following requirements is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). Specifically, we believe that the time, effort, and financial resources necessary to comply with the aforementioned requirements will be incurred by pharmacies during the normal course of their activities and, therefore, should be considered usual and customary business practices.

In § 423.132(a), 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. The information 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.

In § 423.136(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. The burden associated with this requirement is the time and effort necessary to maintain and disclose enrollee records.

Section 423.904(d) 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.

Since the following requirements is associated with an affirmation and certification, the requirements and burden are exempt (5 CFR. 1320.3(h)(1)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

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.

- ICRs Approved Under Other OMB Control Numbers

(No Change)

Burden for the following collections of information are approved by OMB under control number 0938-0936 (CMS-10137).

In § 423.410(e), 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.

In § 423.458(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.

In § 423.458(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.

In § 423.458(d), a cost plan (as defined in § 417.401) or PACE organization (as defined in § 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.

In § 423.502(b), 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.

Burden for the following collections of information are approved by OMB under control number 0938-0944 (CMS-10142).

In § 423.153(d), to become a Part D sponsor, an 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 is captured under § 423.265.

In § 423.265(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.

Burden for the following collections of information are approved by OMB under control number 0938-0957 (CMS-10156).

In § 423.884 (a),(b), (c) and (d), 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.

Burden for the following collections of information are approved by OMB under control number 0938-0977 (CMS-10170).

In § 423.888 (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.

Burden for the following collections of information are approved by OMB under control number 0938-0978 (CMS-10171).

In § 423.464(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 requirements are approved under the subject control number.

Burden for the following collections of information are approved by OMB under control number 0938-0992 (CMS-10185).

In § 423.514, under Validation of Part D Reporting Requirements, the burden estimate for the validation of Part D reporting requirements is under the subject control number.

Burden for the following collections of information are approved by OMB under control number 0938-1013 (CMS-10198).

In § 423.56(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.

Burden for the following collections of information are approved by OMB under control number 0938-0467 (CMS-R-74).

Section 423.774(d) discusses the application requirements for individuals applying for low-income subsidy. 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.

Burden for the following collections of information are approved by OMB under control number 0938-0502 (CMS-R-107).

Section 423.910(c) 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. States must provide accurate and complete coding in their MSIS data submittals.

13. Capital Costs

All states and Part D plan sponsors are fully operational and equipped to fulfill these requirements. Therefore no additional capital or equipment costs will result 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 $744. This is based upon the 2017 Washington-Baltimore-Northern VA Locality Pay Area hourly rate for a GS-11/step 6 of $37.18/hr (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/15Tables/html/DCB_h.aspx) multiplied by the number of burden hours (20).

15. Changes to Burden

The currently approved ROCIS table (approved by OMB on 10/29/2015) incorrectly set out 7,588,143 hours of burden. This was mistakenly carried over from the initial 06/19/2015 Supporting Statement submission. The subsequent 10/27/2015 submission had set out 8,581,027 hours of burden which was in line with the section 12 burden summary table. That table, however, should have set out 8,581,800 hours (a difference of plus 773 hours). The 773 hour error was in the Medicare Prescription Drug Benefit Program (PLAN) burden which should have been 5,704,645 hours instead of 5,703,872 hours.

Correction #1 *(ROCIS Error)*

7,588,143 Currently Approved (hr)
8,581,027 Supporting Statement (10/27/2015)
+992,884 hours

Correction #2 *(Calculation Error)*

Supporting Statement (10/27/2015) Section 12.3

5,703,872 hr (Currently Approved Total)
5,704,645 hr (Corrected Total)
+773 hours

Subtotal #1

8,581,027
+ 773
8,581,800 hours

Burden Adjustments

In section 12.3. (Medicare Prescription Drug Benefit Program: Plans) we propose the following private sector burden adjustments:

Burden Adjustments: Medicare Prescription Drug Benefit Program (Plans)

CFR	Respondents		Responses		Time		
	Currently Approved	Proposed	Currently Approved	Proposed	Currently Approved	Proposed	Difference
423.32(d)	793	757	1,586	1,514	4,758	4,542	-216
			39,540,000	3,954,000	62,218	67,218	-5,000*
423.36(b)	793	757	1,903,752	1,903,752	33,157	33,121	-36
423.44(b)	793	757	793	757	793	757	-36
			793	757	793	757	-36
			793	757	793	757	-36
423.48	793	757	793	757	1,586	1,514	-72

423.104(g)	793	757	793	757	7,930	7,570	-360
423.120(b)	793	757	793	757	1,586	1,514	-72
			793	757	31,720	30,280	-1,440
423.128(a)	793	757	793	757	158,600	151,400	-7,200
423.128(e)	793	757	793	757	126,880	121,120	-5,760
423.153(b)	793	757	793	757	396.5	378.5	-18
423.153(c)	793	757	793	757	396.5	378.5	-18
423.343(c)	793	757	793	757	7,930	7,570	-360
423.343(d)	793	757	793	757	7,930	7,570	-360
423.505(d)	793	757	793	757	41,236	39,364	-1,872
423.505(f)	793	757	793	757	6,344	6,056	-288
423.562(a)	793	757	793	757	6,344	6,056	-288
423.564(g)	793	757	793	757	41,236	39,364	-1,872
423.800(b)	793	757	793	757	61,834	59,046	-2,788
TOTAL	**793**	**757**	**41,459,612**	**5,872,892**	**604,461**	**586,333**	**-18,128**

*Combined correction and adjustment.

Subtotal #2

8,581,800 hr
-18,128 hr (Supporting Statement, Section 12.3)
8,563,672 hours

Program Changes

We also add the following based on the rule's (CMS-4182-F, RIN 0938-AT08) CARA provisions (see section 12.3.10 of this Supporting Statement for details).

CFR Section	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.153(f) (New: CARA)	219	0.083	17.4	3,692	307
423.153(f) (New: CARA)	219	5	1	219	1,095
Total (Private Sector)	**219**	**varies**	**varies**	**3,911**	**1,402**

In the same rule we add new burden associated with the Access to Covered Part D Drugs; Preclusion List. For details see Supporting Statement sections 12.5. (System Programming), 12.6. (Creation of model notices) and 12.7. (Preparation and issuance of model notices).

423.120(c)(6)	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
12.5. System Programming (New)	30	1,040	1	1,040	93,600
12.6. Creation of model notices (New)	212	3	1	212	636
12.7 Preparation and issuance of model notices (New)	950	0.083 (5 min)	varies	95,000	7,885
Total (Private Sector)	**1,192**	**varies**	**varies**	**96,252**	**102,121**

System Programming

For this provision the burden will include the time and effort for Part D adjudication systems to be programmed for the model notices. We estimate that it will take sponsors and PBMs with Part D adjudication systems approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of § 423.120(c)(6). The sponsors and PBMs will need approximately six to twelve months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time Software Developers and Programmers at $98.54 /hr amounts to **93,600 hours** (3 workers x 1,040 hr x 30 sponsors/PBMs) at a cost of **$9,223,344** (93,600 hr x $98.54 /hr) for 2019. This is a one-time burden. There will be no burden associated with 2020 and 2021.

Creation of Model Notices

The finalized provision will require that Part D sponsors provide written notice to the beneficiary and take reasonable efforts to furnish written notice to the prescriber.

For this provision the burden will include the time and effort for creating the model notices. We estimate that 212 parent organizations will need to create two model notices to notify beneficiaries and prescribers under finalized § 423.120(c)(6). We project that it will take each organization 3 hours at $70.28/hr for a business operations specialist to create the two model notices. In aggregate, we estimate a one-time burden of **636 hours** (212 organizations x 3 hr) at a cost of **$44,698** (636 hr x $70.28 /hr) in 2019 or $210.84 per organization ($ 44,698 /212 organizations).).

Preparation and Issuance of Model Notices

The finalized provision will require that Part D sponsors provide written notice to the beneficiary and take reasonable efforts to furnish written notice to the prescriber.

For this provision we estimate that it will take an average of 5 minutes (0.083 hr) to generate and disseminate the aforementioned notice. We estimate that an average of approximately 800 prescribers will be on the Preclusion List in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries will have received prescriptions written by these prescribers and will therefore receive the notice referenced in § 423.120(c)(6). In aggregate, we estimate a burden of **6,640 hours** (0.083 hr/response x 80,000 responses) at a cost of **$ 262,413** (6,640 hr x $39.52 /hr) or $1,273,80 per organization ($ 262,413 / 212 organizations) for an insurance claim and policy processing clerk to prepare and distribute the notices in 2019.

In 2020 and 2021, we estimate that roughly 150 prescribers will be added to the Preclusion List, though this will be largely offset by the same number of prescribers being updated to reflect a change in their preclusion status (for example, based on reenrollment after the expiration of a reenrollment bar) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of **1,245 hours** (15,000 beneficiaries x 0.083 hr) at a cost of **$49,202** (1,245 hr x $39.52 /hr) or $328.02 per prescriber ($ 49,202/150 prescribers))

TOTAL

8,563,672 hr
102,121 hr
+1,402 hr
8,667,195 hours (see section 12)

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

The expiration date for this current package is November 30th, 2021 as displayed on the collection instruments.

18. Certification Statement

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.