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

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BACKGROUND

The PRA requirements referenced in this submission, as reflected in the regulations at 42 CFR Part 423 and the Social Security Act (the Act), assisted in the implementation of the provisions of the Act to establish and regulate the Medicare Prescription Drug Benefit and support the continued administration of the program.

The existing approved package is being revised to update burden estimates based on the number of contracts in Medicare Part D, as well as the expiration date for the Preclusion List letter. The update to the Preclusion List is a non-substantive change and thus does not account for any additional burden. A new section has been added for a new integrated care special enrollment period (SEP) included in the CY 2025 Medicare Advantage and Part D rule (CMS-4205-F, hereafter referred to as the April 2024 final rule) at 42 CFR 423.38.

A new section has been added for a new requirement that MA organizations establish a utilization management committee, which was finalized in the CY 2024 Medicare Advantage and Part D final rule (CMS-4201-F, hereafter referred to as the April 2023 final rule). A new section has been added for additional requirements for the utilization management committee included in the April 2024 rule.

A. JUSTIFICATION

1. Need and Legal Basis

A 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). Section 101 amended Title XVIII of the Act by establishing the new Part D: the Voluntary Prescription Drug Benefit Program. Section 101 of Title I added sections 1860D-1 through D-42 and sections 102, 103, 104 and 109 to the Act. As specified in the MMA, the prescription drug benefit program became available to beneficiaries beginning on January 1, 2006. On January 28, 2005 (70 FR 4194) CMS published a final rule (CMS-4068-F; RIN 0938-AN08) to implement the provisions of the Act and establish and regulate the Medicare Prescription Drug Benefit.

Determination of the IRA temporary retrospective subsidy for contract year 2023 (Section 1860D-15(h) of the Act)

The Inflation Reduction Act of 2022 (IRA) was signed into law on August 16, 2022. Effective January 1, 2023, the IRA eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of $35 per month supply for Part D covered insulin products and eliminates the deductible and all beneficiary cost sharing for Advisory Committee on Immunization Practices (ACIP)-recommended adult vaccines administered in accordance with the ACIP recommendation (hereinafter referred to as “ACIP-recommended adult vaccines”). The IRA mandates that Medicare pay Part D sponsors a temporary retrospective subsidy (hereinafter referred to as “IRA subsidy amount” or “IRASA”) for this reduction in cost sharing and deductible for contract year 2023, which must equal the difference between the beneficiary cost sharing for the covered insulin product or ACIP-recommended adult vaccine under a Part D plan’s 2023 benefit design, which Part D sponsors were required to submit to CMS prior to the passage of the IRA, and the applicable statutory maximum cost sharing limit created by the IRA. For 2023-2025, the IRA allows for the implementation of the insulin and vaccine provisions,

including the related 2023 temporary retrospective subsidy, by program instruction or other forms of program guidance.

In order for CMS to calculate the IRASA, sponsors will need to submit an IRASA reconciliation file to CMS for contract year 2023. The IRASA reconciliation file will be used to calculate the temporary retrospective subsidy for contract year 2023, which CMS will include in the calculation of the sponsors' 2023 Part D payment reconciliation amount, along with other reconciled subsidies (including the reinsurance and low-income cost-sharing subsidies). The file will be collected under a similar timeframe as CMS collects other information that Part D sponsors are required to submit after the completion of a contract year and in preparation for Part D payment reconciliation.

2. Information Users

As explained below, 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.

ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p)

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 because creating such plans is a well-established practice across most industries. We also created a regulation.

ICRs Regarding Medicare Prescription Drug Benefit Program (Beneficiaries)

Those who wish to enroll in a Part D sponsors' plan must submit an enrollment form and an acknowledgement of disclosure of pertinent information to be shared between the Department of Health and Human Services and the Part D sponsor. The enrollee must also provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement.

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. This information comes as written guidance provided to beneficiaries after enrollment, and indicates options available in case a beneficiary wants to appeal a coverage determination or file a grievance.

ICRs Regarding Medicare Prescription Drug Benefit Program (Plans)

Dissemination of Plan Information (§ 423.128)

A beneficiary that has utilized their drug benefit receives an explanation of benefits indicating how cost-sharing is applied to their drugs based on their prescription drug benefit.

Part D sponsors will use information from beneficiaries' history of prescription to provide a list of therapeutic alternatives to pain medications they are taking. Specifically, prescription

information that is entered into a pharmacy at the point-of-sale shows the sponsor the type of medication is taking. They will use this to provide information on the benefits of non-opioid alternatives.

Accreditation Organizations (§ 423.168)

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.

Determination of payment (§ 423.329), Risk sharing arrangements (§ 423.336), Retroactive adjustments and reconciliations (§ 423.343), and the IRA temporary retrospective subsidy for contract year 2023 (1860D-15(h) of the Act)

Part D sponsors are required to submit information to CMS necessary for CMS to perform payment activities under Medicare Part D. Specifically, sponsors must submit cost data that CMS requires within 6 months of the end of a coverage year. See 42 CFR 423.336(c) and 423.343(c) and (d), and generally 1860D-15(f) of the Act. In addition, in order for CMS to pay the statutorily mandated IRA subsidy amount for contract year 2023, Part D sponsors must submit data necessary for CMS to determine that subsidy. See generally section *1860D-15(f) and (h) of the Act.*

ICRs Regarding State Eligibility Determinations (§423.904(b)) and Reporting (§423.910(d))

States are required to make available application forms for low-income subsidy, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. Individuals or personal representatives applying for the low-income subsidy must complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. State agencies are required to inform CMS of LIS eligibility for potential enrollees, and must inform CMS of these cases.

States must provide CMS with this information as specified in order to administer the Part D prescription drug benefit.

ICRs Regarding the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers

To ensure patient protections and safety and to protect the Trust Funds from prescribers and providers identified as bad actors, a Part D plan sponsor must reject, or require its pharmacy benefit manager to reject, a pharmacy claim for a Part D drug if the individual who prescribed the drug is included on the ‘‘preclusion list.’’

CMS issues an initial email notification to the impacted providers using the email addresses obtained from the Provider Enrollment, Chain and Ownership System (PECOS), the Medicare enrollment system of record, or the National Provider Plan and Enumeration System (NPPES). CMS or a Medicare Administrative Contractor (MAC) follows up with a written notice through certified mail to the impacted provider in advance of his or her inclusion on the Preclusion List and their applicable appeal rights.

3. Improved Information Technology

Information collection may involve the use of automated or electronic mechanisms designed to reduce burden and increase efficiency.

Under § 423.505(p), Part D sponsors are required 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. This includes developing contingency plans to maintain the availability and, as applicable, the confidentiality of hard copy and electronic essential records, including a disaster recovery plan for IT and beneficiary communication systems.

Under § 423.153(f)(6)(i), which codified requirements in the Comprehensive Addiction and Recovery Act, the Part D sponsor will send a mailed written notice to indicate a beneficiary's at risk status and whether any restrictions have been imposed on their access to opioids. Where feasible the collection of information involves the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. It is anticipated that sponsors will upload sample letters into automated computer systems so the content is communicated reliably and a digital record of letters being sent is maintained. Communication between the plan sponsor and CMS is conducted electronically through OMS and MARx allowing for detailed DMP data disclosure and maintenance of records. Although responses to CMS regarding outcomes of case management or coverage limitations require manual input into OMS or MARx, respectively, by sponsors, the electronic format eliminates the need for paper submissions.

For appeals and grievances related to coverage determinations, guidance may be delivered by mail or electronically, depending on the beneficiary's preference.

Payment information collected from Part D sponsors under §§ 423.336 and 423.343, as well as payment information collected from Part D sponsors in order for CMS to comply with section 1860D-15(h) of the Act, are collected electronically.

4. Duplication of Similar Information

This collection does not contain duplication of similar information.

5. Small Businesses

We are certifying that this PRA package does not have a significant economic impact on a substantial number of small entities. To defend our position, we first describe at a high level the cash flows related to the Medicare program. We then provide more specific details. The high-level underlying idea in creating the non-government-managed Prescription Drug program (PDPs and drug portion of MA-PDs) is to allow beneficiaries to obtain prescription drugs in a competitive market to reduce costs. For MA, MA-PD and Cost plans, enrollees obtain the same Original Medicare Part A and Part B services they would otherwise obtain in the original Medicare program, albeit at reduced cost (however, for the small percentage of plans bidding above the benchmark, enrollees pay more, but this percentage of plans is not "significant" as defined by the RFA and as justified below).

The savings achieved by the MA-PD plans, the amount of reduced cost, can then be used by the private insurers in a variety of ways, including providing benefits supplemental to original Medicare. Some examples of these supplemental benefits include vision, dental, and hearing. The cost for furnishing these supplemental benefits comes from a combination of the Trust Fund and enrollee premiums.

Part D plans submit bids and are paid by the Medicare Trust Fund for their projected costs in the form of direct premium subsidy and reinsurance. For any enrolled low-income beneficiaries, they receive low-income premium subsidy and low-income cost-sharing subsidy in addition. The national average monthly bid amount, or NAMBA, determines the base premium. A plan's premium is the sum of the base premium and the difference between its bid amount and the NAMBA.

Thus, the cost of providing services by these insurers is met by a variety of government funding and in some cases by enrollee premiums. In order to achieve these goals, the government pays the health plans a portion of the funds that would have been paid had plan enrollees remained in original Medicare. These funds are then used to provide additional benefits on behalf of the health plans' enrollees. Thus, by the original design of the Medicare health plan programs, the various insurance programs were not expected to suffer burden or losses since, in this very unique insurance relationship, the private companies are being supported by the government who, in turn, is saving money because health plans, by virtue of coordinating care, are furnishing the same services, albeit at reduced cost. This lack of expected burden applies to both large and small health plans.

The unique Part D regulations, such as those in this PRA package, are defined so that small entities are not expected to incur additional burden since the cost of complying with any final rule is passed on to the government.

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 plan 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 to, for example, drug utilization management or dissemination of plan information, is an annual requirement; 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.

Testing and revising 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 60-day notice published in the Federal Register 9/10/2024 (89 FR 73420).
No comments were received during the comment period.

The 30-day notice published in the Federal Register 12/3/2024 (89 FR 95797).

9. Payments/Gifts to Respondents

Respondent receiving payment in any form must be in compliance with the information collection requirements set forth.

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 & Costs)

Subsection 12A sets out burden for collection of information requirements that are subject to the PRA. Subsection 12B lists collection of information requirements that are exempt from the PRA. Subsection 12C lists related collection of information requirements that are approved by OMB under a control number other than 0938-0964 (CMS-10141).

12A. Information Collection Requirements and Burden Subject to the PRA This section consists of the following subsections*:*

1. Wage Estimates

2. Requirements and Annual Burden Estimates

a. 12.1 ICRs Regarding the Utilization Management Committee and Health Equity §422.137

b. 12.2 ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p)

c. 12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Beneficiaries)

d. 12.4 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans)
e. 12.5 ICRs Regarding State Eligibility Determinations (§423.904(b)) and Reporting (§423.910(d))
f. 12.6 ICRs Regarding the Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers

3. Summary of Requirements and Annual Burden Estimates

4. 4. Information Collection Instruments, Instructions and Guidance Documents

1. WAGE ESTIMATES

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 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.

Unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Table 1. National Occupational Employment and Wage Estimates

BLS Occupation	Occupation	Mean	Fringe Benefits	Adjusted
Business Operations Specialist, All Other	13-1199	39.75	39.75	79.50
Computer Programmer	15-1251	49.42	49.42	98.84
Compliance Officer	13-1041	37.01	37.01	74.02
General and Operations Manager	11-1021	59.07	59.07	118.14
All Occupations	00-0000	20.71	n/a	n/a
Insurance Claim and Policy Processing Clerk	43-9041	23.00	23.00	46.00
Pharmacist	29-1051	62.22	62.22	124.44
Pharmacy Technician	29-2052	19.35	19.35	38.70
Physicians, All Other	29-1229	114.76	114.76	229.52
Software Developer	15-1250	60.07	60.07	120.14
Software Engineer	15-1252	63.91	63.91	127.82

2. REQUIREMENTS AND ANNUAL BURDEN ESTIMATES

The Collection Requests (ICRs) are being revised to reflect the number of Part D sponsors in contract year 2023. Where applicable, the number of Part D sponsors has been updated to reflect 2023 contract information. In 2023, there were 966 contracts offering Part D (63 standalone PDPs and 903 MA-PD plans). The 966 contracts are represented by 749 legal entities and 306 parent organizations.

a. 12.1 ICRs regarding the Utilization Management Committee and Health Equity §422.137 (New)

12.1.1 Creation of a Utilization Management Committee

Final rule CMS - 4201-F at § 422.137, requires that MA plans establish and use a committee that reviews utilization management (UM) policies annually to ensure the policies are consistent with current traditional Medicare coverage and guidelines in Medicare statutes and regulations, NCDs, and LCDs. The rule also requires that the committee review all medical services that

require PA and other utilization management policies, at least on an annual basis and to document their findings. Additionally, the committee will be responsible for revising and updating the MA plan's utilization management policies as needed.

CMS-4201-F requires at § 422.137(c)(1) through (4) specifies that the UM committee must clearly articulate and document processes to determine that the committee membership requirements under 422.137(c)(1) through (4) have been met, including the determination by an objective party of whether disclosed financial interests are conflicts of interest and the management of any recusals due to such conflicts. We estimate it would take 1 hour at $76.20/hr for an UM Committee business specialist to perform the tasks enumerated in the previous paragraph and review and retain documentation and information on an annual basis. Additionally, at § 422.137(d)(4) and (5) specifies that the committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request. We estimate that it will take 2 hours at $76.20/hr for a UM Committee business specialist to capture and retain this required documentation on an annual basis.

In aggregate, the burden for 697 MA plans is 2,091 hours (697 plans * 3 hr) at a cost of $159,334 (2,091 hr * $76.20/hr).

Table 2. Creation of a Utilization Management Committee: Burden and Cost Summary (Subtotal)

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)	Total Annual Cost ($)
422.137	TPD	697	3	1	697	2,091	159,334
Subtotal	*n/a*	**Varies**	**Varies**	**1**	697	2,091	159,334

12.1.2 Annual Health Equity Analysis

CMS - 4205-F at § 422.137(c)(5), proposes requiring a member of the UM committee to have expertise in health equity. Adding a committee member with expertise in health equity will ensure that policies and procedures are reviewed from a health equity perspective. We estimate that a compliance officer working at $74.02/hr would take 30 minutes for a one-time update of the policies and procedures. In aggregate, we estimate a one-time burden of 483 hours (966 plans * 0.5 hr) at a cost of $35,752 (483 hr * $74.02/hr).

Additionally, 4205-F at § 422.137(d)(6) proposes to require the UM committee to conduct an annual health equity analysis of the use of prior authorization and publicly post the results of the analysis to the plan's website. This would examine the impact of prior authorization, at the plan level, on enrollees with one or more of the following social risk factors: (i) receipt of the low-income subsidy for Medicare Part D, or being dually eligible for Medicare and Medicaid, or (ii) having a disability, as reflected in CMS's records regarding the basis for Medicare Part A entitlement. To gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. The metrics that must be stratified and aggregated for all items and services for this analysis are as follows:

- The percentage of standard prior authorization requests that were approved.
- The percentage of standard prior authorization requests that were denied.
- The percentage of standard prior authorization requests that were approved after appeal.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved.
- The percentage of expedited prior authorization requests that were approved.
- The percentage of expedited prior authorization requests that were denied.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations.

We estimate that a software and web developer working at an hourly wage of $120.14/hr would take 8 hours at a cost of $961 (8 hr * $120.14/hr) for developing the software necessary to collect and aggregate the data required to produce the report. In aggregate, we estimate a one-time burden of 7,728 hr (966 plans * 8 hr/plan) at a cost of $928,442 (7,728 hr * $120.14/hr).

Annually, the report must be produced and posted to the plan's website. The health equity analysis and public reporting must be easily accessible, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); to Annually, the report must be produced and posted to the plan's website. The health equity analysis and public reporting must be easily accessible, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); to automated searches and direct file downloads through a link posted in the footer on the plan's publicly available website, and includes a txt file in the root directory that includes a direct link to the machine-readable file of public reporting and health equity analysis to establish and maintain automated access. We believe that making this information more easily accessible to

automated searches and data pulls and capturing this information in a meaningful way across MA organizations will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information. We assume the plans' programmers will make this an automated process accessing data already in the plans' systems; hence, we estimate minimal time to produce and inspect the report prior to posting. We estimate a Business Operations Specialist working at $79.50/hr would take 0.1667 hr (10 minutes) to produce, inspect, and post the report at a cost of $13 ($79.50/hr * 0.1667 hr). In the aggregate, we estimate an annual burden of 161 hours (966 plans * 0.1667 hr/plan) at a cost of $12,800 (161 hr * $79.50/hr).

Table 3. Annual Health Equity Analysis: Burden and Cost Summary (Subtotal)

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)	Total Annual Cost ($)
422.137	R	966	.5	1	966	483	35,752
422.137	RK	966	8	1	966	7,728	928,442
422.137	TPD	966	.1667	1	966	161	12,800
Subtotal	*n/a*	**966**	**Varies**	**1**	**966**	**8,372**	**976,994**

b. 12.2 ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p)

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.

We estimate that annually there will be 3 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 and already have business continuity plans in place. We estimate a burden of 240 hours for each of these 3 entities for a total burden of 720 hours (240 hr x 3 plans) at a cost of $57,240 (720 hr x $79.50/hr) for a business operations specialist. We also estimate for each subsequent year that 99 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 a total burden of 3,960 hours (40 hr x 99 plans) at a cost of $314,820 (3,960 hr x $79.50/ hr) for a business operations specialist, for a combined total burden of 4,680 hours.

Table 4. Business Continuity Plans: Burden and Cost Summary (Subtotal)

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)	Total Annual Cost ($)
423.505(p) combined with 422.504(o)	RK	3	240	1	3	720	57,240
423.505(p) combined with 422.504(o)	RK	99	40	1	99	3,960	314,820
Subtotal	*n/a*	**102**	**Varies**	**1**	**102**	**4,680**	**372,060**

*RK (recordkeeping)

c. 12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Benes) (§§ 423.32, 423.34, 423.38, 423.56, and 423.578)

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

12.3.1 Enrollment process (§ 423.32)

The burden for this ICR is now accounted for in CMS-10718 (OMB 0938-1378).

12.3.2 Enrollment of full-benefit dual eligible individuals (§ 423.34) (No Change)

Section 423.34© 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). The total number of hours is 32,500 hours for the full dual beneficiaries (130,000 beneficiaries x 0.25 hr) at an annual cost of $673,075 (32,500 hr x $20.71/hr individual hourly wage).

12.3.3 Procedures to document creditable status of prescription drug coverage (§ 423.56) (No Change)

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 0.25 hr) at an annual cost of $518 (25 hr x $20.71/hr individual hourly wage).

12.3.4 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 4,500,000 exception requests will be received annually by 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 1,125,000 hours (4,500,000 requests x 0.25 hr) at an annual cost of $23,298,750 (1,125,000 hours x $20.71/hour individual hourly wage).

12.3.5 Burden Summary

Table 5. Medicare Prescription Drug Benefit Program (Individuals): Burden and Cost Summary (Subtotal)

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
423.34(e)	R	130,000	0.25	1	130,000	32,500	673,075
423.56(f)	R	100	0.25	1	100	25	518

423.578(a) and (b)	R	4,500,000	0.25	1	4,500,000	1,125,000	**23,298,750**
Subtotal	*n/a*	**4,630,100**	**Varies**	**1**	**4,630,100**	**1,157,525**	**23,972,343**

*R (reporting)

d. 12.4 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans) (§§ 423.34, 423.36, § 423.38, 423.44, 423.46, § 423.48, 423.104, 423.120, 423.128, 423.153, 423.168, 423.171, and 423.907, 423.329, 423.336, 423.343, 1860D-15(h) of the Act, 423.464, 423.505, 423.552, 423.562, 423.564, 423.568, 423.570, 423.572, 423.578, 423.800, and 423.892

The notification of enrollment status to a beneficiary is a 3rd party disclosure by the Part D sponsor that is reflected in the plan burden.

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

As noted in section 12.2.2, 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 annual burden is 32,500 hours for a business operations specialist for 966 Part D plan sponsors. The estimated annual cost is $2,583,750 ($79.50/hr x 32,500 hr).

12.4.2 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 966 Part D plan sponsors in 2023. 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. 966 plan sponsors x 1 hour = 966 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) = 33,330 hours. The total number of hours is 33,330 hours (966 + 33,330). The estimated annual cost is $2,649,735.00 ($79.50/hr x 33,330 hr).

12.4.3 Enrollment periods (§ 423.38)

We codified (at § 423.38(c)(11) through (32)) certain Part D SEPs for exceptional circumstances currently set out in sub-regulatory guidance that MA organizations and Part D plan sponsors have implemented and are currently following. We are also establishing two new additional

SEPs for exceptional circumstances: The SEP for Individuals Enrolled in a Plan Placed in Receivership and the SEP for Individuals Enrolled in a Plan that has been identified by CMS as a Consistent Poor Performer.

We estimate it would take approximately 5 minutes (0.083 hr) at $79.50/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for Part D parent organizations associated with standalone PDPs is estimated at 155,627 hours (1,867,519 beneficiary SEP elections * 0.083) at a cost of $12,372,347 (155,627 hours * $79.50/hr).

Burden for MA organizations was submitted to OMB for approval under control number 09380753 (CMS-R-267).

Table 6. Burden Summary for Enrollment Periods (§ 423.38)

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
423.38(c)	SEP Enrollment	R	50	1,867,519	0.083	155,627	79.50	12,372,347

*R (reporting)

*12.4.4 Enrollment periods: Integrated care SEP (§ 423.38) (**New**)*

As described in the October 2023 proposed rule and the April 2024 final rule, we are redesignating § 423.38(c)(35) to § 423.38(c)(36) and proposing a new integrated care SEP at § 423.38(c)(35). The final policy, as described in the April 2024 final rule, narrows the scope from the proposed policy that would have allowed enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans. Instead, the integrated care SEP that we are finalizing at § 423.38(c)(35) will only be available to facilitate aligned enrollment as defined at § 422.2 and we are clarifying in § 423.38(c)(35)(i) that the SEP is available only for full-benefit dual eligible individuals as defined in § 423.772.

The integrated care SEP at § 423.38(c)(35) will require plans to update guidance and train staff. That new burden would be limited to FIDE SNPs, HIDE SNPs, and AIPs. We expect that plans would need one software engineer working 4 hours to update software and one business operations specialist working 4 hours to update plan policies and procedures and train staff in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2025) of 904 hours (113 plans * 8 hr/plan) at a cost of $93,709 (113 plans x [(4 hr* $127.82/hr) + (4 hr * $79.50)]). We do not anticipate any new burden to plans after the initial year.

Table 7. Enrollment Period; Integrated Care SEPs: Burden and Cost Summary (Subtotal)

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
423.38(c)	Integrated Care	R	113	113	4	904	127.82	93,709

*12.4.5 Involuntary disenrollment by the Part D plan (§ 423.44) (**Revised**)*

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 were approximately 966 Part D plan sponsors in 2023. 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. 966 plan sponsors x 1 hour = 966 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. We estimate that on an annual basis 496,344 individuals will be disenrolled for failure to pay premiums. Total burden is 496,344 notices * 0.083 hr (5 minutes each) = 41,197 hours to submit the required transaction to CMS and 496,344 notices x 0.017 hours (1 minute each) = 8,438 hours to disseminate the notice. The total number of hours is 50,601 (966 + 41,197 + 8,438). The estimated annual cost is $ 4,022,779.50 ($79.50 /hr x 50,601 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 DIRMAA), 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 were approximately 966 Part D plan sponsors in 2023. 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. 966 plan sponsors x 1 hour
= 966 hours. We estimate that it will take a Part D plan 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. We estimate that on an annual basis 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 1008.7 (966 + 18.7). The estimated annual cost is $80,192 ($79.50 /hr x 1008.7 hr).

An individual who is disenrolled for non-payment of plan premiums or non-payment Part DIRMAA 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 were approximately 966 Part D plan sponsors in 2023. 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. 966 plan sponsors x 1 hour = 966 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 2,743 (966 + 1,777). The estimated annual cost is $218,068.50 ($79.50 /hr x 2,743 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 exempt from PRA requirements as discussed in section 12B.

*12.4.6 Late enrollment penalty (§ 423.46) (**Revised**)*

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 were approximately 966 Part D plan sponsors in 2023.

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 $78,585,750 ($79.50 /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 $26,090,469 ($79.50 /hr x 328,182 hr).

*12.4.7 Information about Part D (§ 423.48) (**Revised)***

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 966 Part D sponsors 2 hours for a business operations specialist to submit the required documentation to CMS for a total annual burden of 1,932 hours. The estimated annual cost is $ 153,594.00($79.50 /hr x 1,932 hr).

*12.4.8 Requirements related to qualified prescription drug coverage (§ 423.104) (**Revised**)*

(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 966 respondents 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 9,660 hours. The estimated annual cost is $767,970.00 ($79.50 /hr x 9,660 hr).

*12.4.9 Access to covered Part D drugs (§ 423.120) (**Revised**)*

12.4.9.1 Formulary development and revision by a pharmacy and therapeutic committee (423.120(b)(1)) *(No changes)*

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 966 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 1,932 hours. The estimated annual cost is $ 153,594 ($79.50 /hr x1,932 hr).

Medicare Advantage (MA) regulations at 422.136(d) provides protections to help ensure that beneficiaries maintain access to medically necessary Part B drugs while permitting MA plans to implement step therapy protocols that support stronger price negotiation and cost and utilization controls. In order to implement a step therapy program for one or more Part B drugs, this rule

requires that an MA plan establish and use a P&T Committee to review and approve step therapy programs used in connection with Part B drugs. The P&T Committee requirements are very similar to the requirements applicable to Part D plans under § 423.120(b). This rule allows MA- PD plans to use the Part D P&T Committee to satisfy the new requirements related to MA plans and Part B drugs. For MA plans that do not cover Part D benefits already, they may use the Part D P&T Committee of another plan under the same contract. Under § 422.4(c), every MA contract must have at least one plan offering Part D. Because of the small amount of work needed annually, we believe it is reasonable to assume that no new committees will be formed and that the added work will be performed by the existing P&T Committees.

Paragraphs 422.136(b)(4) and (9) require that the P&T Committee "clearly articulate and document processes," We estimate it would take 1 hour at $79.50 /hr for a P&T Committee business specialist to perform certain tasks and review and retain documentation and information. The 1 hour estimate reflects half of the Part D P&T Committee burden (or 2 hours). We believe that the added hour is reasonable since the P&T Committee requires significantly less work for Part B than for Part D. In aggregate, we estimate an annual burden of 906 hours for 876 MA-PD plans (1 hr x [966 total Part D plans minus 60 standalone PDPs which do not offer Part B]) at a cost of $ 72,027 (906 hr x $79.50 /hr).

Table 8 Burden for Part D P&T Committee

Regulatory Citation	Provision Brief Title	Respondents	Response Type*	Total Responses	Hours per Respondent	Total Hours	Labor Cost ($/hr)	Total Annual Cost ($)
423.120,422.136, 422.568,422.570, 422.572,422.584, 422.590, 422.618, and 422.619	Part B Step Therapy (use of P&T Committee)	966	RK	966	1	966	79.50	72,027
423.120(b)(1)	Part D formulary development	966	RK	966	2	1,932	79.50	153,594
TOTAL		**Varies**	**RK**	**Varies**	**Varies**	**2,838**	**79.50**	**225,621**

*RK (recordkeeping)

12.4.9.2 Transition Process (423.120(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 nonformulary 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 $125,371,500 ($79.50 /hr x 1,577,000 hr).

12.4.9.3 Provision of notice regarding formulary changes (423.120(b)(5)) (Removed in CMS 4205-F)

See section 12.4.9.5 Provision of notice regarding formulary changes (423.120(e) and (f))

12.4.9.4 Use of standardized technology (423.120(e)(1))

Under paragraph(e)(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.

12.4.9.5 Provision of notice regarding formulary changes (423.120(e) and (f)) (New CMS-4205-F)

Part D sponsors notify CMS of their intent to make a negative formulary change by submitting a negative change request (NCR) via the Health Plan Management System (HPMS) NCR module. Part D sponsors provide CMS notice of changes which do not require NCRs by submitting updated formulary files during monthly windows, which is a standard formulary management operation. Part D sponsors submit formularies which can be used across multiple contracts and plans. In 2023, CMS approved 542 formularies which were used across 1,556 contracts and 7,048 plans offered by 197 parent organizations. Since there are some efficiencies with respect to formulary management and NCR submissions (for example, NCRs submitted for one formulary can be applied to others in a streamlined manner), we estimate burden at the parent organization level. However, not all Part D sponsors submit NCRs. In 2023, 89 parent organizations submitted 2,642 NCRs for 219 formularies. We believe that generally a pharmacist is responsible for managing NCR submissions and that each NCR takes approximately 5 minutes (0.0833 hr) to submit through the HPMS module, based on CMS internal user testing. In total, for 89 parent organizations, the burden to submit NCRs is estimated to be 220 hours (2,642 NCRs x 0.0833 hr per NCR) at a cost of $ 27,377 ($124.44/hr x 220 hr).

Part D sponsors include immediate formulary changes, approved negative changes, and any enhancements (for example, addition of newly approved drugs, moving a drug to a lower cost-sharing tier, removing or making less restrictive utilization management requirements) to their formularies consistent with formulary requirements. Generally, every formulary is updated during these monthly formulary update windows and CMS reviews all changes to ensure they are consistent with regulatory requirements. Since every parent organization generally updates their formulary regardless of whether any negative changes are made, we estimate burden for all 197 parent organizations representing 542 formularies in 2023. There are 11 formulary update windows per year (monthly from January to November). We believe a pharmacist is generally responsible for managing formulary submissions. In this case, 5,962 formulary submissions (542 formularies x 11 submission windows). We estimate that each formulary file update requires 2

hours to prepare, for a total of 11,924 hours (5,962 submissions x 2 hr per submission) at a cost of $1,483,823 (11,924 hr x $124.44/hr).

Enrollees affected by negative formulary changes are required to receive direct written notice as described at § 423.120(f)(1) and (f)(4), respectively. CMS provides a model "Notice of Formulary Change" which sponsors may use to meet regulatory requirements. Affected enrollees include those who are subject to immediate substitutions and maintenance formulary changes.
The notice requirement is the same, with the exception that enrollees subject to immediate substitutions receive notice retrospectively while enrollees subject to maintenance formulary changes receive notice in advance of the change. There are no affected enrollees subject to non-maintenance changes since these types of changes are permitted only when enrollees taking the drug subject to the non-maintenance change are exempt from the change (that is, "grandfathered") for the remainder of the contract year. In order to estimate the number of affected enrollees, we used 2022 data on the total number of Part D enrollees (across the entire program) taking each drug subject to the negative formulary change during the contract year. We then calculated the estimated number of affected enrollees by prorating the number of enrollees taking the drug across the entire program based on the relative proportion of the Part D plan's enrollment in 2023 to the total Medicare Part D enrollment in 2023. There were 143 parent organizations that implemented immediate substitutions or maintenance formulary changes for 348 formularies used for 528 contracts and 2,298 plans affecting a total of 54,114 enrollees.

We therefore calculate non-labor costs associated with sending notice of formulary change to affected enrollees. Enrollees may opt in to receiving communication materials electronically rather than via hard-copy mailings; however, consistent with informal communication from stakeholders for other required documents, we assume all affected enrollees prefer hard-copy mailings. Costs for hard-copy mailings include paper, toner, envelopes, and postage.

- Cost of paper: We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).

- Cost of toner: We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).

- Cost of Envelopes: We assume a cost of $440 for 10,000 envelopes. The cost per envelope is $0.044.

- Cost of postage: The current cost of first-class metered mail is $0.64 per letter up to 1 ounce. We are using metered mail because these notifications contain confidential beneficiary information and therefore a bulk mailing cannot be used.

A sheet of paper weights 0.16 ounces (5 pounds/500 sheets x 16 ounces/pound). we estimate each mailing to consist of 2 pages or 0.32 ounces, so no additional postage for mailings in excess of 1 ounce is anticipated.

Thus, the aggregate cost per mailing is $.0.7120 ([$0.007 for paper x 2 pages] + [$0.007 for toner x 2 pages] + $0.64 for postage + $0.044 for per envelopes). We estimate the total annual mailing cost at $ $38,529 ($0.7120 per notice x 54,114 affected enrollees).

Table 9. Burden for Provision of Notice Regarding Formulary Changes

Regulatory Citation	Response Summary	Total Respondents	Response Type**	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
§423.120(e)(1)	Submit Negative Change Request	89	R	2,642	0.0833	220	124.44	27,377
§423.120(f)	Update Formulary in HPMS	197	R	5,962	2	11,924	124.44	1,483,823
§423.120(f)(1) and (f)(4)	Direct Written Notice to Affected Enrollees	143	TPD	54,114	n/a	n/a	n/a	38,529*
TOTAL		n/a	Varies	62,718	Varies	12,144	Varies	1,549,729

*Non-labor cost.
**R (reporting), TPD (third party disclosure)

12.4.9 ICRs Regarding the Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6)) (No Changes)

For this provision we estimate that it will take an average of 5 minutes (0.083 hr) at $46.00/hour for an insurance claim and policy processing clerk to generate and disseminate the aforementioned notice.

In 2020 and 2021, we estimated 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 $57,270 (1,245 hr x $46.00 /hr) or $382 per prescriber ($57,270/150 prescribers).

Table 10. Precluded Provider Model Notices Burden and Cost Summary (Private Sector: Subtotal

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annua©ost ($)
423.120(c)(6)	TPD	150	0.083 (5 min)	Varies	15,000	1,245	57,270
Subtotal	*n/a*	**150**	0.083 (5 min)	**Varies**	**15,000**	**1,245**	57,270

*TPD (third party disclosure).

*12.4.10 Dissemination of plan information (§ 423.128) (**Revised**)*

The burden associated with 423.128(a) regarding Part D Explanation of Benefits, has since been extracted from this supporting statement and is now located in CMS-10453.

12.4.10.1 Educating Part D Beneficiaries on Opioid Risks and Alternative Treatments (423.128(b)(11)) (No Changes)

Parent organizations may disclose the opioid and coverage information in electronic form, but only so long as the enrollee has consented to receiving plan information in electronic form. Some enrollees prefer electronic notification and some prefer paper mailing. We have no way of estimating the proportions for each preference, but our experience suggests that most enrollees expect a paper mailing. Therefore, we assume 75 percent (the average of 50 percent and 100 percent) would prefer a paper mailing, while the remaining 25 percent would prefer electronic mailing.

Part D sponsors are permitted to send this information to all or a subset of their enrollees, however for the purposes of estimating burden, it was assumed that Part D parent organizations will send the required information to all enrollees so as to not underestimate burden. The total number of Part D enrollees was calculated to be 50,765,562 based on 2023 enrollment.

In making estimates on the burden of sending out notices, we assumed that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs are paper, toner, and postage for 38,074,172 enrollees (50,765.562 x 75 percent of enrollees who are assumed to prefer paper). We also assumed one page per notice. We therefore estimate:

- *Cost of paper:* Typical wholesale costs of paper are approximately $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500).
- *Cost of toner:* Toner costs can range from $50 to $200 and each toner cartridge can last from 4,000 to 10,000 sheets of paper. In this rule, we assume a cost of $70 for 10,000 pages. In that regard, the cost per page is $0.007 ($70/ 10,000 pages).
- *Cost of postage:* Currently, the bulk postage rates are $0.12 per 1,000 pages. The cost per page is $0.00012 ($0.12/ 1000 pages).

Thus, the aggregate cost per page is $0.01412 ($0.007 for paper + $0.007 for toner + $0.00012 for postage). The total annual mailing costs are $537,608 ($0.01412 per notice x 38,074,172 enrollees).

12.4.10.2 Posting Updated Formulary on Plan Website (423.128(d)(2)(ii) and (iii)) (New, CMS-4205-F)

Requirements for Part D sponsors' internet website include the current formulary for the Part D plan, updated at least monthly consistent with § 423.128(d)(2)(ii), and advance notice of negative formulary changes for current and prospective enrollees, consistent with § 423.128(d)(2)(iii). Online postings that are otherwise consistent with requirements for notice to other specified entities may constitute sufficient notice of negative formulary changes. To estimate burden associated with providing notice of formulary changes to other specified entities, we calculate the time and cost associated with updating the formulary and providing notice of drugs affected by negative formulary changes (such as a summary table which lists

such changes) on the Part D sponsor's website. For 542 formularies in 2023, monthly updates would be posted at least 12 times annually for a total of 6,504 postings (542 formularies x 12 updates/year) by all 197 parent organizations. We estimate that it would take 1 hour to update the website consistent with the requirements at § 423.128(d)(2)(ii) and (iii) and that a computer programmer would be responsible for such postings for a total annual burden of 6,504 hours (6,504 updates x 1 hr/update) at a cost of $642,855 ($98.84/hr x 6,504 hr).

Table 11. Burden Summary for Dissemination of Plan Information (§ 423.128)

Regulatory Citation	Provision Brief Title	Respondents	Response Type**	Total Responses	Hours per Response	Total Hours	Labor Cost ($/hr)	Total Annual Cost ($)
423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Sending Materials Out by Mail)	306	TPD	38,074,172	N/A	N/A	N/A	537,608
423.128(d)(2)(ii)-(iii)	Updating Formulary and Providing Online Notice of Changes on Website	197	TPD	6,504	1	6,504	98.84	642,855
TOTAL	*n/a*	**Varies**	**NA**	**38,077,814**	**Varies**	**Varies**	**Varies**	**575,222.42**

*Non-labor requirements and costs

**R (reporting), RK (recordkeeping), and TPD (third party disclosure)

***Annualized burden

12.4.11 Drug Utilization Management, Quality Assurance, Medication Therapy

*Management (MTM), and Drug Management Programs (§ 423.153) (**Removed**)*

The burden associated with Drug Utilization Management, Quality Assurance, Medication Therapy Management, and Drug Management Programs has been extracted from this package and is now located in CMS-10874.

12.4.12 Accreditation Organizations and Treatment of Territories (§ 423.168, 423.171, and 423.907) (*No Change*)

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. Under 423.171 any organization applying for approval must furnish to CMS all of the information and materials set forth in this part.

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 burden associated with these requirements is the time and effort necessary for a sponsoring entity to submit the required information to CMS. On an annual basis it will take 7 accreditation organizations and 5 territories about 1 hour per month each for a business operations specialist to submit the required notification to CMS, for a total of approximately 144 hours (144 total hours x12 responses/yr x (7 accreditation organizations + 5 territories)). The estimated annual cost is $11,448 ($79.50 /hr x 144 hrs).

12.4.13 Determination of payment (§ 423.329) (***Revised***)

Paragraph (b) requires 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 63 stand-alone Part D plan contracts and 149 PACE contracts (for a total of 212 respondents) 52 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 11,024 hours. The estimated annual cost is $876,408 ($79.50 /hr x 11,024 hr).

Paragraph (b)(ii) requires 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 927 MA-

PD contracts 15 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 13,905 hours. The estimated annual cost is $1,105,448 ($79.50
/hr x 13,905 hr).

12.4.14 Risk sharing arrangements (§ 423.336) (***Revised***)

(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 $7,950 ($79.50 /hr x 10©r).

(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 966 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 115,920 hours (966 sponsors x 10 hours x 12 submissions per year). The estimated annual cost is $111,978,720.00 ($79.50 /hr x 115,920).

12.4.15 Retroactive adjustments and reconciliations (§ 423.343) (***Revised***)

(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 966 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 9,660 hours. The estimated annual cost is $767,970.00($79.50 /hr x 9,660 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 966 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 9,966 hours. The estimated annual cost is $767,970 ($79.50/hr x 9,660 hr).

12.4.15.1 Determination of the IRA temporary retrospective subsidy for contract year 2023 (section 1860D-15(h) of the Act) ***(No Change)***

Effective January 1, 2023, the IRA eliminates the deductible and imposes a statutory maximum beneficiary cost sharing of $35 per month supply for Part D covered insulin products and eliminates the deductible and all beneficiary cost sharing for ACIP-recommended adult vaccines administered in accordance with the ACIP recommendation. The IRA also mandates that Medicare pay Part D sponsors a temporary retrospective subsidy for this reduction in cost sharing and deductible for contract year 2023, which must equal the difference between the beneficiary cost sharing for the covered insulin product or ACIP-recommended adult vaccine under a Part D plan's 2023 benefit design, which Part D sponsors were required to submit to CMS prior to the passage of the IRA, and the applicable statutory maximum cost sharing limit created by the IRA. See generally 1860D-15(h) of the Act. In order for CMS to pay the statutorily mandated IRA temporary retrospective subsidy (i.e., IRA subsidy amount or "IRASA") for contract year 2023, Part D sponsors must submit data necessary for CMS to determine that subsidy through the IRASA reconciliation file.

The burden associated with the IRASA reconciliation file relates to compiling and sending the file to CMS. The reconciliation file will only be submitted for contract year 2023. Only sponsors that have a mix of IRASA and non-IRASA Other TrOOP amounts reported on the prescription drug event (PDE) record will need to submit a reconciliation file. Also, given how the PACE program is structured, whereby they can charge no cost sharing under their 2023 benefit designs and thus will receive no IRASA, it will not be necessary for PACE plans to submit a reconciliation file and, therefore, they will not be included in the burden estimate. We estimate that on an annual basis it will take 841 respondents (Part D sponsors excluding PACE) four hours for a business operations specialist to maintain the required documentation on an annual basis, for total annual burden of 3,364 hours. The estimated annual cost is $267,438 ($79.50 /hr x 3,364 hr).

12.4.16 Coordination of benefits with other providers of prescription drug coverage (§ 423.464) (*No Change*)

§ 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 captured and discussed in PRA package CMS-10718.

12.4.17 Contract provisions (§ 423.505) (***Revised***)

(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 966 respondents 52 hours for a business operations specialist to maintain the required documentation on an annual basis, for total annual burden of 50,601 hours. The estimated annual cost is $4,022,779.50 ($79.50 /hr x 50 hr).

(12) (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 966 respondents 8 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of 7,728 hours. The estimated annual cost is $614,376 ($79.50 /hr x 7,728hr).

12.4.18 Novation agreement requirements (§ 423.552) (*No Change*)

§ 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 inclusive of burden associated with § 423.551, which is exempt from PRA requirements as it affects fewer than 10 respondents, as discussed in section 12B.

12.4.19 General Provisions (§ 423.562) (***Revised***)

(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 966 Part D plan sponsors to disclose the necessary information to enrollees. We estimate that it will require each of the 966 Part D plan sponsors 8 hours for a business operations specialist to disclose the information for a total annual burden of hours. The estimated annual cost is $614,376 ($79.50 /hr x 7,728 hr).

12.4.20 Grievance procedures (§ 423.564) (***Revised***)

(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 752 Part D plan sponsors will provide notification of a total of 531,000 grievance decisions annually. 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 sponsors

will have to provide written notification to enrollees in 53,100 grievances and oral notification in 477,900 grievances. We estimate it will take 30 minutes (0.5 hours) to provide written notification for a total annual burden of 26,550 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 119,475 hours. The total number of hours is 146,025(26,550 + 119,475) annually. The estimated annual cost is $11,608,988 ($79.50/hr x 146,025 hr).

(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 752 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 39,104 hours. The estimated annual cost is $3,108,768($79.50 /hr x 39,104 hr).

12.4.21 Standard timeframe and notice requirements for coverage determinations (§ 423.568) (***Revised***)

(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. Based on more current data, we are updating our estimates that Part D plan sponsors will receive about 9,700,000 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 966 Part D plan sponsors a total of 91,875 hours to perform this function on an annual basis. The estimated annual cost is $ 7,304,063($79.50 /hr x 91,875 hr).

(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, 'he 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 966 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 $73,040,705 ($79.50 /hr x 918,751 hr).

12.4.22 Expediting certain coverage determinations (§ 423.570) (***Revised***)

(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 966 Part D plan sponsors 58,188 hours to perform this function on an annual basis. The estimated annual cost is $4,625,946 ($79.5 / hr x 58,188 hr).

(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 966 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 $243,508 ($79.50 /hr x 3,063 hr).

12.4.23 Timeframes and notice requirements for expedited coverage determinations (§ 423.572) (***Revised***)

(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 966 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 $24,103,446 ($79.50 /hr x 303,188 hr).

12.4.24 Exceptions process (§ 423.578) (***Revised***)

Exception requests must be supported 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 $137,066,590 ($229.52/hour x 597,188 hour).

12.4.25 Administration of subsidy program (§ 423.800) (***Revised***)

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 966 respondents approximately 52 hours for a business operations specialist to provide the information to CMS for a total of 50,23250,601 hours annually. The estimated annual cost is $4,022,779.50 ($79.50/hr x 50,232 hr).

We also estimate that it will take approximately 26 hours for each of the 966 respondents to maintain the information for tracking purposes for a total of 25,116 hours annually. The estimated annual cost is $1,996,722.00 ($79.50/hr x 25,116 hr).

12.4.26 Change in Ownership (§ 423.892) (***Revised***)

(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 10 entities (1 percent of 966) about 1 hour for a business operations specialist to submit the required notification to CMS, for a total of approximately 10 hours. The estimated annual cost is $795 ($79.50 /hr x 10 hr).

12.4.27 Burden Summary for ICRs Regarding Medicare Prescription Drug Benefit Program (Plans)

Table 12. Medicare Prescription Drug Benefit Program (Private Sector/Plans): Burden Summary (Subtotal)

Regulatory and Statutory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
422.137	R	697	3	1	697	2,091	159,334
		966	.5	1	966	483	35,752
423.36(b)	R	966	0.017	2,021	1,903,752	33,330	2,649,735
			1	1	966	966	76,797
423.38(c)	R	50	0.083	37,350	1,867,519	155,627	12,372,347
423.38(c)(35)	R	113	4	1	113	452	35,934
		113	4	1	113	452	57,775
423.44(b)	R	966	0.083	527	496,344	50,601	4,027,779.50
423.46(b)	R	966	0.25	4,197	3,954,000	988,500	78,585,750
423.48	R	966	2	1	966	1,932	153,594
423.104(g)	R	966	10	1	966	9,660	767,970
423.153(b)	R	966	0.5	1	966	495	39,353
423.153(c)	R	966	0.5	1	966	495	39,353
423.153(f)	R	306	0.0167	117	35,771	597	23,104
423.168(c) 423.171(a) 423.904(a)	R	12	1	12	144	144	11,448
423.329(b)	R	212	52	1	212	11,024	876,408
		927	15	1	927	13,905	1,105,448
423.336(a)	R	5	20	1	5	100	7,950
423.336(c)	R	966	10	12	11,800	115,920	9,444,600
423.343(c)	R	966	10	1	966	9,660	767,970
423.343(d)	R	966	10	1	966	9,660	767,970
1860D-15(h) of the Act	R	841	4	1	841	3,364	267,438
423.505(f)	R	966	8	1	966	7,920	614,376
423.800(b)	R	966	52	1	966	50,601	4,022,779.50

Regulatory and Statutory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
423.892(c)	R	10	1	1	10	10	795
Subtotal (Reporting)		***varies***	***varies***	***varies***	***8,281,908***	***1,467,989***	***116,911,760***
423.46(d)	RK	966	0.083	4,197	3,954,000	328,182	26,090,469
423.120(b)	RK	966	2	1	966	1,932	153,594
423.120(d)	RK	906	1	1	906	906	72,027
423.128(a)	RK	966	80	1	966	79,200	6,296,400
423.153(d)(1)(vii)(E)	RK	942	2	1	314**	628 **	78,149
		942	2	1	314**	628 **	62,072
423.153(f)	RK	306	5	117	35,771	178,855	19,881,522
423.505(d)	RK	966	52	1	966	50,601	4,022,779.50
423.564(g)	RK	752	52	1	752	39,104	3,108,768
423.568(a)(3)	RK	966	0.05	1,951	1,837,500	91,875	7,304,063
423.570(c)(2)	RK	966	0.05	1,235	1,163,750	58,188	4,625,946
423.570(d)	RK	966	0.25	13	12,250	3,063	243,508
423.800(b)	RK	966	26	1	966	25,740	1,931,373
Subtotal (Record keeping)		***varies***	***Varies***	***Varies***	***7,008,793***	***858,902***	***73,870,671***
Regulatory and Statutory Citation	**Response Type***	**# Respondents**	**Time (hr per response)**	**# Responses (per respondent)**	**Total Responses (all respondents)**	**Total Annual Time (hr, all respondents)**	**Total Annual Cos©$)**
423.34(e)	TPD	966	0.25	138	130,000	152,717	2,583,7502
423.44(b)	TPD	966	1	1	966	71,009	80,192
		966	0.017	527	496,344	6,108,682	683,972
		966	1	1	966	24,771	76,359
		966	0.017	1	1,100	18,882	1,516
		966	1	1	966	75,762	76,359
		966	0.1	19	17,772	57,751	144,044
		966	40	1	966	3,980,579	3,148,200

423.120(b)	TPD	966	0.083	20,170	19,000,000	5,628	125,371,500
423.128(b)(11)	TPD	306	n/a	115,920	38,074,172	N/A	537,608
Regulatory and Statutory Citation	**Response Type***	**# Respondents**	**Time (hr per response)**	**# Responses (per respondent)**	**Total Responses (all respondents)**	**Total Annual Time (hr, all respondents)**	**Total Annual Cos©$)**
423.153(d)(1)(vii)(E)	TPD	942	n/a	995	937,495	7,447,388	13,238
423.153(f)	TPD	306	0.1667	26	7,911	1,319	51,046
		11	1	1	11	11	426
423.562(a)	TPD	966	8	1	966	1,985,322	614,376
423.564(e)	TPD	752	0.5	14	53,100	26,550	13,275
		752	0.25	126	477,900	119,475	11,608,988
423.568(b), (c), (d), and (f)	TPD	966	0.25	1,209	1,139,250	284,813	22,642,634
		966	0.25	2,692	2,535,750	633,938	50,398,071
423.572(a) and (c)	TPD	966	0.25	1,287	1,212,750	303,188	24,103,446
423.578	TPD	n/a	0.25	n/a	2,388,750	597,188	137,066,590
Subtotal (Third Party Disclosure)	n/a	***varies***	***Varies***	***Varies***	***66,477,135***	***21,894,973***	***402,469,342***
TOTAL (R, RK, and TPD)	n/a	***varies***	***Varies***	***Varies***	***81,767,836***	***24,221,864***	***593,251,773***

*R (reporting), RK (recordkeeping), and TPD (third party disclosure). **Annualized burden and cost

e. 12.5 ICRs Regarding State Eligibility Determinations (423.904(b)) and Reporting (423.910(d)) (Revised)

12.5.1 Eligibility determinations for low-income subsidies (§ 423.904) (***Revised***)

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 at a cost of $486,540 (6,120 hr x $79.50 /hr for a business operations specialist). 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.

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 at a cost of $81,090

(1,020 hr x $79.50 /hr for a business operations specialist). 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.

12.5.2 Requirements (§ 423.910) (***Revised***)

(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 $486,540 ($79.50 /hr x 6,120 hr).

12.5.3 Burden Summary for ICRs Regarding State Eligibility Determinations and Reporting

Table 13. State Eligibility Determinations Burden and Cost Summary (States: Subtotal)

Regulatory Citation	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
423.904(b)	R	51	10/month	12,000	600,000	6,120	486,540
	R		20	1	51	1,020	81,090
423.910(d)	R	51	10/month	12	51	6,120	486,540
Subtotal	*n/a*	**51**	**Varies**	**varies**	**600,102**	**13,260**	**1,054,170**

*R (reporting)

f.

3. SUMMARY OF REQUIREMENTS AND ANNUAL BURDEN AND COST ESTIMATES

Table 14. Burden and Cost Estimates

ICR Section	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
12.1 Utilization Management Committee and Health Equity	1,663	varies	varies	1,663	10,463	1,136,328

§422.137 *(New)*, from Table						
12.2. Business Continuity Plans (*Revised*), from Table 2	102	Varies	1	102	4,680	372,060
12.4. Medicare Prescription Drug Benefit Program: Plans (*Revised*), from Table 11	966	Varies	Varies	81,767,836	24,221,864	***593,251,773***
12.6 Preparation and issuance of Precluded Provider model notices (*Revise*d), from Table 14	150	0.083	Varies	15,000	1,245	57,270
Subtotal (Private Sector)	*2,881*	*Varies*	*Varies*	*81,784,601*	*24,238,252*	*594,817,431*
12.3. Medicare Prescription Drug Benefit Program: Bene (*Revised*), from Table 3	4,630,100	Varies	1	4,630,100	1,157,525	23,972,343
Subtotal (Individuals and Households)	*4,630,100*	*Varies*	*1*	*4,630,100*	*1,157,525*	*23,972,343*
12.5. State Eligibility Determinations (Revised), from Table 13	51	Varies	Varies	600,102	13,260	1,054,170
Subtotal (States)	*51*	*Varies*	*Varies*	*600,102*	*13,260*	1,054,170
TOTAL	**4,633,032**	**Varies**	**Varies**	**87,014,803**	**25,409,037**	**619,843,944**

4. INFORMATION COLLECTION INSTRUMENTS, INSTRUCTIONS AND GUIDANCE DOCUMENTS

Drug Management Program Standardized Notices and Model Letters ***(Removed)***

(See section 12.4.11 Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs)

- Instructions for Drug Management Program Notices ***(Removed from this package)***
- Initial Notice Sent to Potentially At-Risk Beneficiaries ***(Removed from this package)***

- Second Notice Sent to Beneficiary Designating At-Risk Status ***(Removed from this package)***
- Alternate Second Notice Sent to Beneficiary Not Considered At-Risk ***(Removed from this package)***
- Model Prescriber Inquiry Letter ***(Removed from this package)***
- Model Sponsor Information Transfer Memo ***(Removed from this package)***

Model Precluded Provider Letter (No Change)

(See section 12.6, Preparation and Issuance of Model Notices)

Part D Explanation of Benefits ***(Removed from this package)***

(See section 12.4.10, Medicare Prescription Drug Benefit Program: Plans, Dissemination of Plan Information)

12B. Information Collection Requests Exempt from the Paperwork Reduction Act (Revised)

Exemptions Pertaining to Nine or Fewer Respondents

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.).

Part D Optional Disenrollment for Fraud and Abuse

Section 423.44(d)(9)(i) establishes that if an individual provides fraudulent information on his or her election form or permits abuse of his or her enrollment card, the Part D plan has the option to involuntarily disenroll the individual. Section 423.44(d)(9) also establishes the process for optional disenrollment for an individual who commits fraud or permits abuse of their enrollment card. Section 423.44(d)(9)(ii) establishes that a Part D plan that opts to disenroll an individual who commits fraud or permits abuse of their enrollment card must provide the individual a written notice of the disenrollment that meets the notice requirements set forth in § 423.44(c). Section 423.44(d)(9)(iii) establishes that a Part D plan must report to CMS any disenrollment based on fraud or abuse by the individual.

We estimate that it will take a Part D plan three hours to capture and retain the required documentation for each occurrence of disenrollment for fraud and abuse. Since 2012, there have been only five disenrollments for fraud and abuse. Three of those disenrollments were from MA/MAPD plans, one was from the Limited Income Newly Eligible Transition (LI NET) program, and one was from a standalone Part D plan. Thus, the burden to Part D plans is negligible and, per 5 CFR 1320.3(c), not subject to PRA because it involves less than 10 entities per year.

All information impacts related to providing written notice to the member and notifying CMS of the disenrollment have already been accounted for under OMB control numbers 0938–0964 (CMS–10141).

Enrollment Periods

In paragraph § 423.38 (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.

Terminations and Non-Renewals of Part D Contracts

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 a manner that meets the requirements of this section, each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective.

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.

There were 0 to 2 nonrenewals for standalone PDP contracts annually between 2019 and 2021. Nonrenewals for MA-PD contracts are accounted for in CMS-R-267 Nonrenewal of contract (§ 422.506). There were 0 to 2 terminations for standalone PDP contracts annually between 2019 and 2021. There were 1-4 terminations for MA-PD contracts annually between 2019 and 2021. Terminations for MA-PD contracts are accounted for in CMS-R-267 noting that provisions § 422.508, § 422.510, § 422.512 are exempt from PRA requirements.

Change in Ownership of Part D Contracts

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.

There were 4-6 changes in ownership (novations) annually between 2019 and 2021 for MA-PD contracts. No changes of ownership took place for standalone PDP contracts between 2019 and 2021.

Waiver of Part D Plan Requirements for U.S. Territories

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.

Fallback Entities

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.

Exemptions Pertaining to Administrative Actions

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.

Exemptions Pertaining to Usual and Customary Business Practices

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. Since the information must be provided after the requirements will be incurred by pharmacies when the drug is dispensed in the normal course of their business practices, or, in the case of dispensing by mail order, at the time of delivery of the drug we believe they are exempt from PRA. 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.

Exemptions Pertaining to Affirmation and Certification

Since the following requirements are 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.). Neither entail burden other than that necessary to identify the respondent, the date, the respondent's address, and the nature of the instrument.

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.

12C. Related collection of information requirements that are approved by OMB under a control number other than 0938-0964 (CMS-10141)

Enrollment Process (§ 423.32). ICRs related to the Enrollment Process requirements at § 423.32 are accounted for in CMS-10718 (OMB 0938-1378).

Enrollment Periods (§ 423.38). ICRs related to burden for MA organizations were submitted to OMB for approval in CMS-R-267 (OMB 0938-0753).

Nonrenewal of Contracts (§ 423.507(a), § 423.508(b), § 423.509(b), and § 423.510(a). ICR related to burden for MA organizations are accounted for in CMS-R-267 (OMB 0938-0753) in ICR for § 422.506. This package also affirms the number of respondents for contract terminations consistent with § 422.508, § 422.510, § 422.512 is less than 10 for MA organizations and therefore exempt from PRA requirements.

Safe disposal of Controlled Substances for MTM Program Enrollees (§ 423.153(d)(1)(vii)(E). The burden associated with operationalizing the requirements for MTM programs is discussed in CMS-10396 (OMB 0938-1154).

Coordination of benefits with other providers of prescription drug coverage (§ 423.464). The burden associated with this requirement is captured and discussed in CMS-10718 (OMB 09381378).

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 $875. This is based upon the 2023 Washington-Baltimore-Northern VA Locality Pay Area hourly rate for a GS-11/step 6 of $43.72/hr (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2023/general-schedule/) multiplied by the number of burden hours (20).

15. Changes to Burden

This section notes revisions from the April 2024 rule using more current beneficiary and plan information, as well as adjustments to burden hours for dissemination of Part D plan information.

The previously approved supporting statement contained 690,557,096 responses and 25,506,943 burden hours. We are revising this estimate to 87,014,803 responses and 25,409,037 burden hours (see Table 15). Total responses decreased by 603,542,293 (690,557,096 –87,014,803) and the annual burden hours decreased by 97,906 (25,506,943-25,409,037). The net change in responses and burden primarily reflects the extraction of §423.128(b), Part D Explanation of Benefits, and §423.153 Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs, from this package. In addition, 4205-F proposes changes to the SEP under §423.38(c)(35) that are accounted for in this package. Changes are also indicated for Utilization Management Committees under §422.137. We also note the revisions in burden estimate due to fewer Part D contracts in 2023 compared to 2022 (990 in 2022 and 966 in 2023).

Table 15: Summary of Response Changes

Responses		
Previous	**Revised**	**Difference**
690,557,096	87,014,803	603,542,293

Hours		
Previous	**Revised**	**Difference**
25,506,943	25,409,037	97,906

15.1 Enrollment periods: Integrated care SEP (§ 423.38)

The purpose of these additions is to account for new, one-time burden to FIDE SNPs, HIDE SNPs, and AIPs related to a new integrated SEP proposed at § 423.38(c)(35) under the April 2024 final rule. The integrated care SEP would create more opportunities for enrollment in integrated D-SNPs through which an individual could receive Medicare and Medicaid services and care coordination from the same organization. This accounts for an additional 904 burden hours and cost of $93,709.

Table 16: Changes to SEP

Subject (Regulatory/Statutory Citation)	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Total Annual Cost ($)
423.38(c) Integrated Care	113	113	4	904	93,709
SUBTOTAL: ADDITION	113	113	4	904	93,709

15.2 Part D Explanation of Benefits (§ 423.128)

The purpose of this revision is to account for changes to the Part D Dissemination of Plan Information, specifically the Part D Explanation of Benefits. This ICR has been extracted and moved to CMS-10453, and results in a net reduction of burden hours for this package of 198,000 hours. Additionally, one-time burden estimates associated with this provision have been fulfilled since this ICR's inception in 2019, thus further decreasing burden hours.

Table 17: Extraction of Part D EOB

Reduced Burden				
Subject (Regulatory/Statutory Citation)	**# Responses (per respondent**	**Total Responses (all respondents)**	**Total Annual Time (hr)**	**Total Annual Cost ($)**
Dissemination of Part D Plan Information (§§ 423.128) Explanation of Benefits	80	990	79,200	356,616
	120	990	118,800	256,337

SUBTOTAL: REDUCTIONS	**200**	990	**198,000**	**612,953**

15.3 Utilization Management Committee (§ 422.137)

The purpose of this revision is to add in a requirement, the reference to which was inadvertently left out of proposed rule CMS-4201-P. The oversight was corrected in the final rule, CMS-4201-
F. The changes are therefore being submitted to OMB for approval under control number 0938–0964 (CMS–10141). We are adding 8,372 additional burden hours for this revision.

Table 18: Addition of Utilization Management Committee

Subject (Regulatory/Statutory Citation)	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)	Total Annual Cost ($)
Utilization Management Committee (§ 422.137)	966	.5	1	966	483	35,752
Utilization Management Committee (§ 422.137)	966	8	1	966	7,728	928,442
Utilization Management Committee (§ 422.137)	966	.1667	1	966	161	12,800
Subtotal	**varies**	**Varies**	**1**	**966**	**8,372**	**976,994**

15.4 Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs (§ 423.153)

The purpose of this revision is to account for changes to the Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs (§ 423.153). This ICR has been extracted and posted under 10874, and results in a net reduction of burden hours for this package. Additionally, one-time burden estimates associated with this provision have been fulfilled since this ICR's inception in 2019, thus further decreasing burden hours burden by 1,587 and costs by 97,252.

Table 19: Extraction of Drug Utilization Management, Quality Assurance, Medication Therapy Management, and Drug Management Programs

Reduced Burden				
Regulatory and Statutory Citation	**# Responses (per respondent)**	**Total Responses (all respondents)**	**Total Annual Time (hr, all respondents)**	**Total Annual Cost ($)**
Changes associated with extraction of Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs 423.153© 423.153(f)	1	990	495	37,719
	1	990	495	37,719
	117	35,771	597	21,814
Subtotal	***varies***	37,751	1,587	97,252

15.5 Grievance Procedures (§ 423.564)

The purpose of this revision to revise burden estimates for grievance procedures that require Part D plan sponsor to 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. We are adding an additional 399,000 burden hours for this ICR to reflect more current grievance estimates.

Table 20: Revision of Grievance Procedures

CFR Section	**Hours**		
	Previous	**Revised**	**Difference**
423.564	132,000	531,000	399,000

15.6 Removal of Burden for Provision of Notice Regarding Formulary Changes (423.120(b)(5)) from section 12.4.9.3 (CMS-4205-F)

Table 21: Extraction of Burden for Provision of Notice Regarding Formulary Changes

Regulatory Citation	**Response Summary**	**Total Respondents**	**Total Responses**	**Time per Response (hr)**	**Total Annual Time (hr)**	**Wage ($/hr)**	**Total Annual Cost ($)**
§423.120(b)(5)(i)	Provide Notice of Formulary Change to CMS and Other Specified Entities	990	990	40	39,600	79.50	3,148,200

15.7 Addition of Burden for Provision of Notice Regarding Formulary Changes (423.120(e) and (f)) and Posting Updated Formulary on Plan Website (423.128(d)(2)(ii) and (iii)) (CMS-4205-F)

Table 22: Addition of Burden for Provision of Notice Regarding Formulary Changes and Posting Updated Formulary on Plan Website

Regulatory Citation	Response Summary	Total Respondents	Total Responses	Time per Response (hr)	Total Annual Time (hr)	Wage ($/hr)	Total Annual Cost ($)
§423.120(e)(1)	Submit Negative Change Request	89	2,642	0.0833	220	124.44	27,377
§423.120(f)	Update Formulary in HPMS	197	5,962	2	11,924	124.44	1,483,823
§423.128(d)(2)(ii)-(iii)	Updating Formulary and Providing Online Notice of Changes on Website	197	6,504	1	6,504	98.84	642,855
§423.120(f)(1) and (f)(4)	Direct Written Notice to Affected Enrollees	143	54,114	n/a	n/a	n/a	38,529

16. Publication and Tabulation Dates

CMS does not intend to publish data related to the collection of information's.

17. Expiration Date

The expiration date is displayed on the collection instruments (see section 12, above).

18. Certification Statement

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

Not applicable.