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

Note: This 2021 collection of information request seeks to extend the November 30, 2021, expiration date for three years as it is associated with two final rules and with 60- and 30-day Federal Register notices that provided the public with additional time to review and comment.

BACKGROUND

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

The purpose of this submission is to request approval of changes to burden estimates, changes to standardized beneficiary notices for drug management programs, and to request a three year extension of the current expiration date for this collection of information. The finalized changes to the standardized notices would take effect on January 1, 2022 pending OMB approval. This iteration makes changes associated with two final rules: CMS-4190-F1 (RIN 0938-AT97) that published in the Federal Register on June 2, 2020 (85 FR 33796); and CMS-4190-F2 (RIN 0938-AT97) that published in the Federal Register on January 19, 2021 (86 FR 5864).

Importantly, in an effort to provide the public with additional time to review and comment we also published a 60-day Federal Register notice on July 21, 2021 (86 FR 38485) and a 30-day notice on October 26, 2021 (86 FR 59165). Comments on the 30-day notice must be received by November 26, 2021.

Summary of Rule (CMS-4190-F1 and F2) Changes (Requirements/Burden)

Special Election Periods (SEPs) for Exceptional Conditions (§ 423.38)

Sections 1851(e)(4) and 1860D-1(b)(3) of the Act establish special election periods (SEPs) during which, if certain circumstances exist, an individual may request enrollment in, or disenrollment from, MA and Part D plans. The Secretary also has the authority to create SEPs for individuals who meet other exceptional conditions.

CMS finalized regulatory changes that codify a number of SEPs we previously adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs provides transparency and stability to the MA and Part D programs by ensuring that the SEPs are known and changed only through additional rulemaking. Among the finalized SEPs are the SEP for Individuals Affected by a FEMA-Declared Weather-Related Emergency or Major Disaster, the SEP for Employer/Union Group Health Plan (EGHP) elections, and the SEP for Individuals Who Disenroll in Connection with a CMS Sanction.

Educating Part D Beneficiaries on Opioid Risks and Alternative Treatments (§ 423.128(b)(11))

Beginning January 1, 2022, 42 CFR § 423.128(b)(11) requires Part D plan sponsors to disclose to all enrollees information about the risks of prolonged opioid use and coverage of non-pharmacological therapies, devices, and non-opioid medications under their plan (MA-PDs) or under their plan and under Medicare Parts A and B (standalone PDPs). Under 42 CFR § 423.128(b)(11)(ii), sponsors are permitted to disclose this information to a subset of enrollees rather than all enrollees.

Safe Disposal of Controlled Substances for Medication Therapy Management (MTM) Program Enrollees § 423.153(d)(1)(vii)(E)

CMS issued a final rule (86 FR 5864)[1] on January 19, 2021, that implements changes to the MTM program beginning January 1, 2022. The final rule expands the definition of beneficiaries targeted for MTM to include at-risk beneficiaries (ARBs) under a Drug Management Program (DMP), regardless of whether those individuals meet other MTM targeting criteria. It also requires plans to provide all MTM enrollees with information about the safe disposal of prescription drugs that are controlled substances, including opioids.

Drug Management Programs (DMPs) (§ 423.153(f))

Pursuant to requirements of the Substance Use Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act, CMS finalized regulatory changes to the Part D drug management program requirements. Under § 423.153(a), all Part D sponsors are required to have a DMP no later than January 1, 2022. Burden is estimated for Part D sponsors who had not voluntarily adopted DMPs under existing regulatory authority. Additionally, beginning January 1, 2022, sponsors are required to include Part D enrollees with a history of opioid-related overdose in their DMPs under § 423.153(f)(16)(ii)(2). Burden is estimated for all Part D sponsors (those who have already voluntarily implemented DMPs and those who will be required to implement DMPs consistent with the regulatory requirement).

Summary of Non-Rule Changes (Requirements/Burden)

Drug Management Programs

In 2013, CMS issued detailed guidance to Part D sponsors which included expectations that CMS had for sponsors to address the urgent opioid crisis.[2] This guidance was issued pursuant to § 423.153(b) which requires Part D plan sponsors to have established a reasonable and appropriate drug utilization management program that maintains policies and systems to assist in preventing over-utilization of prescribed medications and provides CMS with information concerning the procedures and performance of its drug utilization management program.

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management programs (DMPs) for

1 "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Program, and Programs of All-inclusive Care for the Elderly" (CMS 4190-F2)

2 https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-overutilization-monitoring-system-oms-summary

beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). In final rule CMS-4182-F published in the Federal Register on April 16, 2018, CMS established the framework under which Part D sponsors may implement a DMP. This rule codified existing guidance, including the retrospective Part D Drug Utilization Review (DUR) policy and Overutilization Monitoring System (OMS), with adjustments necessary to comply with CARA, by integrating them with the DMP provisions now at 42 CFR § 423.153(f). The purpose of this non-rule-related revision to this package is to quantify burden specific to voluntary adoption of DMPs consistent with 4182-F that had not previously been accounted for. This non-rule-related revision accounts for the change in parent organizations who developed DMPs voluntarily and also reflects more current understanding of the staff involved in DMP activities.

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.

Special Election Periods (SEPs) for Exceptional Conditions (§ 423.38)

Section 1860D–1(b)(1)(B) of the Act directs us to adopt enrollment rules "similar to (and coordinated with)" those under Part C. Accordingly, in addition to those SEPs described above, we have applied certain SEPs established under the MA program to the Part D program. The SEPs from the MA program that have been codified for Part D include the following:

- The Part D plan sponsor's contract is terminated by the plan sponsor or by CMS or the plan is no longer offered in the area where the individual resides (§ 423.38(c)(6)).
- The individual is no longer eligible for the Part D plan because of a change in his or her place of residence to a location outside of the Part D plan region(s) in which the plan is offered (§ 423.38(c)(7)).

Section 1860D-1(b)(3)(C) of the Act also grants the Secretary the authority to create SEPs for individuals who meet other exceptional conditions, which is reflected at § 423.38(c)(8)(ii). Pursuant to this authority, we have codified SEPs for the following circumstances:

- The individual demonstrates to CMS that the plan sponsor substantially violated a material provision of its contract in relation to the initial coverage limit and the out-of-pocket threshold for the current year.

In line with Section 1860D–4(a)(1)(A)(4), the May 23, 2019 (84 FR 23832) final rule (CMS-4180-F) revised § 423.120(d) for Part B Step Therapy and § 423.128(e)(5) for Part D Explanation of Benefits.

Educating Part D Beneficiaries on Opioid Risks and Alternative Treatments (§ 423.128(b)(11))

Pursuant to § 1860D-4(a)(1), CMS finalized a regulation at 42 CFR § 423.128(b)(11) that requires Part D Sponsors to disclose information on risks associated with prolonged opioid use and coverage of non-pharmacological therapies, devices, and non-opioid medications under their plan (MA-PDs) or under their plan and under Medicare Parts A and B (standalone PDPs). Under 42 CFR § 423.128(b)(11)(ii), sponsors are permitted to disclose this information to a subset of enrollees rather than all enrollees.

Safe disposal of Controlled Substances for MTM Program Enrollees (§ 423.153(d)(1)(vii)(E))

Under our finalized revisions to § 423.153(d) to implement sections 6064 and 6103 of the SUPPORT Act, ARBs, as defined in § 423.100 will be targeted for enrollment in a sponsor's MTM program.· programs Section 6103 of the SUPPORT Act amended MTM requirements in 1860D-4(c)(2)(B) of the Act by creating subsection (ii) which requires Part D plans to provide all MTM targeted individuals with information about the safe disposal of controlled substances, including information on drug takeback programs, in-home disposal, and cost-effective means for disposal. Burden associated with providing safe disposal information as part of the MTM comprehensive medication review/standardized format is discussed in a separate information collection request CMS-10396, OMB 0938-1154. Remaining burden associated with providing safe disposal information that is not part of the MTM comprehensive medication review/standardized format, is described in this package.

Drug Management Programs (§ 423.153(f))

Section 704 of the Comprehensive Addiction and Recovery Act (CARA) of 2016 included provisions permitting Part D sponsors to establish drug management programs (DMPs) for beneficiaries at-risk for misuse or abuse of frequently abused drugs (FADs). In final rule CMS-4182-F published in the Federal Register on April 16, 2018, CMS established the framework under which Part D sponsors could implement a DMP. Pursuant to sections 2004 and 2006 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act, respectively, Part D sponsors are required to implement DMPs and include beneficiaries with a history of opioid-related overdose in DMPs.

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)

Part D sponsors are required to maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices. Evidence of these mechanisms must be submitted to CMS, and must demonstrate the ability to restore business operations in case of a natural disaster, emergency, or any other disruption that would otherwise affect their ability to conduct business.

Additionally, sponsors that have existing business continuity plans that do not meet all the requirements must revise and document this information and changes to CMS.

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 drugs 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 explanation of benefits (EOB) of therapeutically equivalent medications that may cost less for the beneficiary.

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.

Drug Management Program Standardized Beneficiary Notices and Sample Letters (§ 423.153(f)(16))

The Comprehensive Addiction and Recovery Act requires Part D sponsors that participate in a drug management program to develop notices to be sent to prescribers informing them of any beneficiary believed to be abusing opioids based on clinical criteria, as well as notifying the beneficiary of this.

In order to determine which beneficiaries would be included in their drug management programs, Part D plans will engage in case management of potential at-risk beneficiaries, through contact with their prescribers, when such beneficiary is found to be taking a specific dosage of opioids and/or obtaining them from multiple prescribers and multiple pharmacies who may not know about each other.

The sponsor will provide an initial notice to a potential at-risk beneficiary if the sponsor intends to limit the beneficiary's access to coverage for frequently abused drugs, and the sponsor will provide a second notice to an at-risk beneficiary when it actually imposes a limit on the beneficiary's access to coverage for frequently abused drugs. Alternatively, the sponsor will provide an alternate second notice if it decides not to limit the beneficiary's access to coverage for frequently abused drugs.

Under DMPs, Part D sponsors will use the authority provided under *§* 423.153(f) to communicate with prescribers in the course of case management and to communicate to enrollees regarding risk status and potential coverage limitations. Information will also be used by for Part D sponsors to convey information about the a prior sponsor's findings about the beneficiary's prior opioid and/or benzodiazepine utilization, and to provide the new sponsor with the records and actions generated by the former sponsor's review of the beneficiary under its DMP.

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 will issue 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) will follow 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. These strategies 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.

Section 423.128(e) requires information on therapeutic alternatives to be included on a beneficiary’s explanation of benefit when their drug benefit is utilized in a given month. This information can be mailed or delivered electronically, depending on the beneficiary’s preferred method of delivery.

4. Duplication of Similar Information

This collection does not contain duplication of similar information.

5. Small Businesses

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

6. Less Frequent Collection

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

For example, under the information collection on business continuity plans, existing plan sponsors are required to annually test their plan and update these documents as needed. New plan sponsors without existing business continuity plans must develop and implement such plans. Business continuity plans ensure that plan sponsors are able to restore business operations after disruptions caused by events such as natural or man-made disasters, systems failures and emergencies. In another example information collected from beneficiaries is collected when an enrollment application is filed and when a coverage determination is requested. Other information, such as other payers reimbursing Part D costs on the enrollee's behalf, is collected from beneficiaries only annually. Information from Part D sponsors related 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.

Conducting testing of business continuity plans less frequently than annually increases the risks associated with a service disruption to beneficiary access to care and coverage. Some other consequences of less frequent collection would be improper or erroneous payment to Part D plans, improper enrollment of beneficiaries in a Part D organization, release of misleading information regarding the health care coverage through a plan to potential members, and inadequate provision of patients' rights to Medicare-covered services.

7. Special Circumstances

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

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,

- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Serving as the 60-day notice, the proposed rule (CMS-4190-P; RIN 0938-AT97) published in the Federal Register on February 18, 2020 (85 FR 9002).

Final rules CMS-4190-F1 and F2 published in the Federal Register on June 2, 2020 (85 FR 33796) and January 19, 2021 (86 FR 5864), respectively.

Public feedback was solicited on the proposed rule (CMS-4190-P) to assist with the development and implementation of the provisions associated with the final rules. The final rules reflect revisions related to comments received.

In the proposed and final rules, one-time burden was not annualized, rather, it was described as "first-year costs" and "subsequent year costs." While these costs are annualized for the purpose of this package, the true burden incurred to sponsors is unchanged, despite the difference in how it was displayed in the proposed and final rules. The proposed rules contained 2019 sponsor information and wages, which are being updated to 2021 (or 2020, where appropriate) sponsor information and 2020 wages. While this changes burden estimates, there were no comments related to the overall methodology used in the proposed rule, so we believe updating to more current sponsor information and wages is a valid approach.

Importantly, in an effort to provide the public with additional time to review and comment we also published a 60-day Federal Register notice on July 21, 2021 (86 FR 38485) and a 30-day notice on October 26, 2021 (86 FR 59165). With regard to the 60-day notice, comments were received and are attached to this collection of information request along with our response. Comments on the 30-day notice must be received by November 26, 2021.

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:

Wage Estimates
Requirements and Annual Burden Estimates
12.1 ICRs Regarding Business Continuity Plans under §§ 422.504(o) and 423.505(p) ***(Revised)***
12.2 ICRs Regarding Medicare Prescription Drug Benefit Program (Beneficiaries) ***(Revised)***
12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans) ***(Revised)***
12.4 ICRs Regarding State Eligibility Determinations (§423.904(b)) and Reporting (§423.910(d))
(No Changes)
12.5 ICRs Regarding the Part D Sponsor's System Programming ***(Removed)***
12.6 ICRs Regarding the Creation of Precluded Provider Model Notices to the Medicare

Beneficiaries and Prescribers
(Removed))
12.7 ICRs Regarding the Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers
(Revised)

Summary of Requirements and Annual Burden Estimates
Information Collection Instruments, Instructions and Guidance Documents

WAGE ESTIMATES

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 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 Title	**Occupation Code**	**Mean Hourly Wage ($/hr)**	**Fringe Benefits and Overhead ($/hr)**	**Adjusted Hourly Wage ($/hr)**
Business Operations Specialist	13-1198	40.53	40.53	81.06
Computer Programmer	15-1251	45.98	45.98	91.96
General Operations Manager	11-1021	60.45	60.45	120.90
All Occupations	00-0000	27.07	n/a	n/a
Insurance Claim and Policy Processing Clerk	43-9041	21.67	21.67	43.34
Pharmacist	29-1051	60.32	60.32	120.64
Physicians, All Other	29-1228	105.22	105.22	210.44
Software Developers	15-1256	54.94	54.94	109.88

REQUIREMENTS AND ANNUAL BURDEN ESTIMATES

The following Information Collection Requests (ICRs) are being revised: Business Continuity Plans (section 12.1), Enrollment Periods (section 12.3.4), Dissemination of plan information (section 12.3.10), Drug Utilization Management, Quality Assurance, and Drug Management Programs (section 12.3.11). As explained within this document, the changes are associated with

CMS 4190-F1 and F2 final rules, as well as non-rule changes. ICRs for the Enrollment process (sections 12.2.1 and 12.3.1), Part D Sponsor's System Programming (section 12.5), and Creation of Precluded Provider Model Notices (section 12.6) were removed from this package as the burden was associated with another PRA package or was one-time burden that was already approved. Where applicable, the number of Part D sponsors has been updated to reflect 2021 contract information. In 2021, there are 942 contracts offering Part D (66 standalone PDPs and 876 MA-PD plans). The 942 contracts are represented by 742 legal entities and 308 parent organizations.

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

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 9 new Part D sponsors and MA organizations that do not already have a business continuity plan based on our experience that most entities that create new plans each year are under parent organizations that already have business continuity plans in place. We estimate a burden of 240 hours for each of these 9 entities. We also estimate that 5 entities with existing plans will either experience a problem or for some other reason update their plan and it will take each plan 40 hours for these revisions. For each subsequent year, we estimate 9 entities will not have the plans in place and it will take 240 hours each to fulfill the business continuity requirements, for a total burden of **2,160 hours** (240 hr x 9 plans) and a total cost of **$175,090** (2,160 hr x $81.06/ hr for a business operations specialist). We also estimate for each subsequent year 5 entities with existing plans will need to update their business continuity plans and it will take 40 hours for each plan to make these revisions, for a total burden of **200 hours** (40 hr x 5 plans) at a cost of **$16,212** (200 hr x $81.06/ hr for a business operations specialist).

Table 2. Business Continuity Plans: Burden and Cost Summary (: Subtotal)

CFR Section	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	RK	9	240	1	9	2,160	175,090
		5	40	1	5	200	16,212

422.504(q)							
Subtotal		**14**	**Varies**	**1**	**14**	**2,360**	**191,302**

*RK (recordkeeping).

12.2 ICRs Regarding Medicare Prescription Drug Benefit Program (Benes) (§§ 423.32 (Removed), 423.34, 423.38, 423.56, and 423.578) ***(Revised)***

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

12.2.1 Enrollment process (§ 423.32) (Removed, see section 15 of this Supporting Statement for details)

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

12.2.2 Enrollment of full-benefit dual eligible individuals (§ 423.34) (No change)

Section 423.34(e) states that a full-benefit dual eligible beneficiary may decline automatic enrollment in a Part D plan or may enroll in a plan different than the plan into which CMS placed them.

The burden associated with this requirement is the time and effort put forth by the individual to actively decline enrollment or to actively enroll in a new, and for plans to process the enrollments and disenrollments. We estimate it will take an individual about 15 minutes (0.25 hours) to, either contact the plan to disenroll or contact the new plan to enroll (resulting in an automatic disenrollment from the plan into which the person was enrolled by CMS). Beneficiaries can contact plans in a number of ways, with varying amounts of time needed for the contact. A beneficiary will need to contact the plan only once. There are, on average, approximately 130,000 individuals who choose their own plan instead of the automatic enrollment each year so we estimate that it takes full dual beneficiaries 32,500 hours each year to decline the automatic enrollment or enroll in a different plan (causing a disenrollment). 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 **$879,775** (32,500 hr x $27.07/hr individual hourly wage).

12.2.3 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 **$667** (25 hr x $27.07/hr individual hourly wage).

12.2.4 Exceptions process (§ 423.578) (No change)

In paragraphs (a) and (b) an enrollee, the enrollee's representative, or the enrollee's prescribing physician or other prescriber (on behalf of the enrollee) may file a request for an exception that meets the requirements of this section.

The burden associated with this requirement is the time and effort necessary for an individual to submit an exception request. We estimate that that 3,185,000 exception requests will be received 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 **796,250 hours** (3,185,000 requests x 0.25 hr) at an annual cost of **$21,554,488** (796,250 hr x $27.07/hr individual hourly wage).

12.2.5 Burden Summary

Table 3. Medicare Prescription Drug Benefit Program (Individuals): Burden and Cost Summary (Subtotal)

CFR Section	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	879,775
423.56(f)	R	100	0.25	1	100	25	677
423.578(a) and (b)	R	3,185,000	0.25	1	3,185,000	796,250	21,554,488
Subtotal		**3,315,100**	**Varies**	**1**	**3,315,100**	**828,775**	**22,434,939**

*R (reporting)

12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans) (§§ 423.32 (Removed), 423.34 (No change), 423.36 (No change), § 423.38 ***(New),*** *423.44 (No change), 423.46 (No change), § 423.48 (No change), 423.104 (No change), 423.120 (No change), 423.128* ***(Revised)****, 423.153* ***(Revised)****; 423.168, 423.171, and 423.907 (No change), 423.329 (No change), 423.336 (No change), 423.343 (No change), 423.464 (No change), 423.505 (No change), 423.552 (No change), 423.562 (No change), 423.564 (No change), 423.568 (No change), 423.570 (No change), 423.572 (No change), 423.578 (No change), 423.800 (No change), and 423.892 (No change)).*

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.

12.3.1 Enrollment process (§ 423.32) (Removed, see section 15 of this Supporting Statement for details)

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)

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 942 Part D plan sponsors. The estimated annual cost is $2,634,450 ($81.06 /hr x 32,500 hr).

12.3.3 Disenrollment process (§ 423.36) (No change)

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 are942 Part D plan sponsors in 2021. 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. 942 plan sponsors x 1 hour = **942** hours. We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) for a business operations specialist to assemble and disseminate the notice for each disenrollment. 1,903,752 notices x 0.017 hours (1 minute each) = **32,364** hours. The total number of hours is **33,306 hours** (942 + 32,364). The estimated annual cost is $2,699,767 ($81.06/hr x 33,306 hr).

12.3.4 Enrollment periods (§ 423.38) ***(New)***

We are codifying (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 $81.06/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 $12,615,091 (155,627 hours * $81.06/hr).

Burden for MA organizations was submitted to OMB for approval under control number 0938-0753 (CMS-R-267).

Table 4. 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	81.06	12,615,091

*R (reporting)

12.3.5 Involuntary disenrollment by the Part D plan (§ 423.44) (No change)

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 942 Part D plan sponsors in 2021. 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. 942 plan sponsors x 1 hour = **942 hours**. We estimate that it will take a Part D plan 5 minutes (0.083 hours) to submit the required transaction to CMS for each occurrence and 1 minute (0.017 hours) for a business operations specialist to assemble and disseminate the notice for each disenrollment. Based on disenrollment data for January through June 2017, we estimate that on an annual basis 496,344 individuals will be disenrolled for failure to pay premiums. 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 **50,576** (942 + 41,197 + 8,438). The estimated annual cost is **$4,099,723** ($81.06 /hr x 50,576 hr).

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

The burden associated with this requirement is the time and effort for the Part D plan sponsor to disclose to an individual the notice of disenrollment. There were approximately 608 Part D plan sponsors in 2020. 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. 942 plan sponsors x 1 hour = **942 hours**. We estimate that it will take a Part D plan 1 minute (0.017 hours) to assemble and disseminate the notice for each disenrollment. Based on data from January 1 through September 23, 2017, we estimate that on an annual basis 1,100 individuals will be disenrolled for failure to pay Part D-IRMAA. 1,100 notices x 0.017 hours = **18.7 hours**. The total number of hours is **960.7** (942 + 18.7). The estimated annual cost is **$77,784** ($81.06 /hr x 960.7 hr).

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

The Part D plan sponsor burden associated with this requirement is the time and effort for the Part D plan sponsor to provide an individual the notice of the owed plan premium amount required for reinstatement. There were approximately 942 Part D plan sponsors in 2021. 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. 942 plan sponsors x 1 hour = **942 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 **2,719** (942+ 1,777). The estimated annual cost is **$220,402** ($81.06 /hr x 2,719 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.

12.3.6 Late enrollment penalty (§ 423.46) (No change)

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 942 Part D plan sponsors in 2021. 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 $80,127,810 ($81.06 /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 **$26,602,433** ($81.06 /hr x 328,182 hr).

12.3.7 Information about Part D (§ 423.48) (No Change)

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 942 Part D sponsors 2 hours for a business operations specialist to submit the required documentation to CMS for a total annual burden of **1,884 hours**. The estimated annual cost is **$152,717** ($81.06 /hr x 1,884 hr).

12.3.8 Requirements related to qualified prescription drug coverage (§ 423.104) (No change)

(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 942 respondents 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,420 hours**. The estimated annual cost is **$763,585** ($81.06 /hr x 9,420 hr).

12.3.9 Access to covered Part D drugs (§ 423.120)(No change)

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

The burden associated with this requirement is the time and effort necessary for a Part D sponsor's pharmacy and therapeutic committee to document and retain the documentation that meets the requirements set forth in this section. We estimate that it will take 942 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 **1,884 hours**. The estimated annual cost is **$152,717** ($81.06 /hr x1,884 hr).

Prior to removing a covered Part D drug from its plan's formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D plan sponsor must provide at least 30 days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage (as described in § 423.464(f)(1)), authorized prescribers, network pharmacies, and pharmacists.

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to provide notice of at least 30 days to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies, and pharmacists of the removal of a covered Part D drug from its formulary.

Given that each entity has already created disclosure notices for mass mailings, we estimate that on an annual basis it will take on average, each of the 942 respondents 40 hours for a business operations specialist to disclose the required notice for a total annual burden of **37,680 hours**. The decrease in total annual burden from the estimate previously reported is due to the decreased number of respondents. The estimated annual cost is **$3,054,341** ($81.06 /hr x 37,680 hr).

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

associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide a notice to beneficiaries regarding the transition process. We estimate this will result in 19 million notices that will take an average of 5 minutes (0.083 hours) for a business operations specialist to prepare. Thus, we estimate the total burden to be **1,577,000 hours**. The estimated annual cost is **$127,831,620** ($81.06/hr x 1,577,000 hr).

Under paragraph (c)(1), a Part D sponsor must issue and reissue, as necessary, a card or other type of technology to its enrollees to use to access negotiated prices for covered Part D drugs.

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

Paragraph (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 (b)(4) and (9) require that the P&T Committee "clearly articulate and document processes," We estimate it would take 1 hour at $81.06/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 **876 hours** for 876 MA-PD plans (1 hr x [942 total Part D plans minus 66 standalone PDPs which do not offer Part B]) at a cost of **$71,009** (876 hr x $81.06/hr).

Table 5. Burden for Part B Step Therapy Use of Part D P&T Committee

Regulatory Reference	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,	Part B Step Therapy (use of PT Committee)	876	RK	876	1	876	81.06	71,009

422.590, 422.618, and 422.619								

*RK (recordkeeping)

12.3.10 Dissemination of plan information (§ 423.128) (Revised)

423.128(a): Dissemination of Part D plan information (No change)

Under paragraph (a), part D sponsors must disclose information about its Part D plan(s) as required by this section to each enrollee of a Part D plan offered by the Part D sponsor under this part and to Part D eligible individuals. The burden associated with this requirement is the time and effort necessary for a Part D sponsor to disclose information and materials about its Part D plan(s). We estimate that it will require 942 respondents 80 hours on an annual basis for a business operations specialist to prepare the plan materials for a total annual burden of **75,360 hours** (942 x 80 hours) and an estimated annual cost of $6,108,682 ($81.06/hr x 75,360 hr). We further estimate that, on average, it will require each contract 120 hours for a business operations specialist to disseminate the required materials to enrollees and eligible individuals for a total annual burden of **113,040 hours * (942 x 120 hr)** and an estimated annual cost of **$9,163,022** ($81.06 /hr x 113,040 hr).

*423.128(b)(11): Educating Part D Beneficiaries on Opioid Risks and Alternative Treatments **(New)***

Part D and MA-PD parent organizations have to create and upload materials into their internal systems. We estimate that 308 Part D and MA-PD parent organizations would be subject to this proposal, based on 2021 data. This is an increase in the burden estimates associated with final rule 4190-F2 as the ICR in that rule was based off of 2019 data (288 parent organizations).

We estimate a one-time burden of 2 hours at $120.64/hr for a pharmacist to develop the materials to be sent to the beneficiaries. In aggregate we estimate a **one-time burden of 616 hours** (308 parent organizations x 2 hr) at a cost of **$74,314** (616 hr x $120.64/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), these will be minor and may only occur in some future years. Hence, the more accurate approach adopted by us here is that we are scoring this as a one-time update). The total hours and cost for this one-time burden is annualized over 3 years (**205 hours and $24,771**, respectively) for the purposes of the summary table in section 12.3.27 of this package.

We estimate that it will take on average 2 hours at $91.96/hr for a computer programmer to upload the information into the systems. This would result in a one-time burden of **616 hours** (2 hr x 308 parent organizations) at a cost of **$56,647** (616 hours x $91.96/hr). Once the information is uploaded into the parent organization's database, we anticipate no further cost associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The automation would include the sending of information to those enrollees who wish to receive an electronic copy. The automation would also cover updates in future years as the plan enrollment changes. The total hours for this one-time burden is annualized over 3 years (**205 hours and $18,882**, respectively) for the purposes of the

summary table in section 12.3.27 of this package.

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 48,595,217 based on 2021 enrollment. This is an increase from the enrollment included in the ICR for final rule 4190-F2 which was based off of 2019 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 36,446,413 enrollees (48,595,217 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 $2.50 for a ream of 500 sheets. The cost for one page is $0.005 ($2.50/500).

• *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 $50 for 10,000 pages. In that regard, the cost per page is $0.005 ($50/ 10,000 pages).

• *Cost of postage:* Currently, the bulk postage rates are $0.19 per 200 pages. The cost per page is $0.00095 ($0.19/ 200 pages).

Thus, the aggregate cost per page is $0.01095 ($0.005 for paper + $0.005 for toner + $0.00095 for postage). The total annual mailing costs are **$399,088** ($0.01095 per notice x 36,446,413 enrollees).

*423.128(e): Furnishing EOB to Enrollees **(Revised)***

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

CMS provides model EOB templates to Part D sponsors that reflect recent policy changes (if any). CMS issues a yearly HPMS memo to Part D sponsors to announce the release of the EOB materials. CMS highlights the changes, if applicable, and posts the model materials, including instructions, on the Part Model Materials website, located at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-

D-Model-Materials. All documents used by Part D sponsors must be compliant with CMS requirements. EOB model materials are included in this package as attachments 3a-3h. A revised package was not submitted for 2021 EOB materials, so crosswalks indicate changes from the approved 2020 EOB materials to the 2022 EOB materials.

The burden associated with this requirement is the time and effort necessary for 942 respondents to provide an explanation of benefits when prescription drug benefits are provided to enrollees. We estimate that it will require each contract 160 hours for a business operations specialist to disseminate the required materials for total annual burden of **150,720 hours**. The estimated annual cost is **$12,217,363** ($81.06/hr x 150,720 hr).

In accordance with § 423.128(e)(5) as codified through CMS-4180-F, sponsors are required to include the cumulative percentage change in the negotiated price since the first day of the current benefit year for each prescription drug claim in the EOB. Sponsors are also required to include information about drugs that are therapeutic alternatives with lower cost-sharing.

EOBs containing additional information about alternatives require more printed pages per EOB. There are currently 48,595,217 Part D enrollees in 2021. For our estimates of paper, toner, and postage we are adopting the same estimates that we used on April 16, 2018 (83 FR 16440) for our CY 2019 MA (Part C)/Prescription Drug Benefit (Part D) final rule (CMS-4182-F, RIN 0938-AT08) found on page 16695. However, we are revising the postage rate to the updated 2021 bulk mailing rates.

Although our regulations allow electronic submission of Part D EOBs upon request, informal communication from stakeholders indicates small usage. We are therefore assuming mailings to all enrollees. Since we do not require first class postage for Part D EOBs, we are assuming that Part D sponsors will use the least expensive option, namely, the use of bulk mailing rates. We also assume that the added information about alternatives is not started on a separate page as that could be costly; accordingly, we assume the current Part D EOB on average ends mid-page and that adding 1-2 pages would on average add 1.5 pages of print requiring at most 1 page of paper (since the other half page of print would go on an already printed page). Furthermore, we assume that the Part D EOB is double-sided. In some cases the extra 1.5 pages may fit on the last printed page and on its other side not necessitating more paper. Bulk mailing rates vary by vendor; an informal survey on the web suggests $0.19 for 2021 rates for 50 pounds (envelope weight is normally considered negligible when citing these rates). Other assumptions are possible but the main drivers of our added cost are paper and toner as opposed to postage. The following breaks down those costs:

- Paper costs $0.005 per sheet ($2.50 for a ream of paper with 500 sheets).
- Toner costs $0.005 per sheet ($50 for a toner cartridge lasting 10,000 sheets).
- Postage costs are $0.000038 per page since--

++ A sheet of paper weights 0.16 ounces (5 pounds/500 sheets x 16 ounces/pound).
++ Commercial bulk postage rates for 2021 are $0.19 for 200 pieces (50 pounds).
++ There are 16 ounces in one pound.
++ Postage cost per page is therefore $0.000038 ([$0.19 x 0.16 ounces per page] / [50 pounds x 16 ounces/pound]).

Thus, the total cost per page is $0.010038 ($0.005 for paper + $0.005 for toner + $0.000038 for postage). Finally, we note that Part D EOBs are sent out once per month to each enrollee summarizing drug transactions for the previous month. Thus we estimate an annual cost of **$5,853,585** (48,595,217million enrollees x 12 months x 1 page x $0.010038 per page). We believe that after appropriate programming (as discussed previously) the 583,142,604 million annual mailings (48,595,217 x 12 per year) will be performed automatically and will not require extra staff time.

Table 6. Burden Summary for Dissemination of Plan Information (§ 423.128)

Regulatory Reference	Provision Brief Title	Respondents	Response Type**	Total Responses	Hours per Respondent	Total Hours	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.128(a)	Developing Plan Information and Materials	942	RK	942	80	75,360	81.06	6,108,682
§ 423.128(a)	Developing Plan Information and Materials	942	TPD	942	120	113,040	81.06	9,163,022
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Programming Updates)	308	RK	308	2	205***	91.96	18,882***
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Developing Materials)	308	RK	308	2	205***	120.64	24,771***
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Sending Materials Out by Mail)	308	TPD	36,446,413	N/A	N/A	N/A	399,088*
§ 423.128(e)	Part D EOB	942	TPD	942	160	150,720	81.06	12,217,363

§ 423.128(e)(5)	Part D EOB (Extra mailings)*	308	TPD	583,142,604	NA	NA	NA	5,853,585*
TOTAL		**Varies**	**NA**	**619,592,459**	*varies*	**339,530**	*Varies*	**33,785,393**

*Non-labor requirements and costs
**R (reporting), R (recordkeeping), and TPD (third party disclosure).
***Annualized burden

12.3.11 Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs (§ 423.153) *(Revised)*

§ 423.153(b) (No change):

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

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor or MA organization offering an MA-PD plan to provide CMS with information concerning its drug utilization management program, according to guidelines specified by CMS. We estimate that it will require 942 respondents 30 minutes (0.5 hours) for a business operations specialist to provide the required material to CMS for consideration for a total annual burden of **471 hours**. The estimated annual cost is **$ 38,179** ($81.06 /hr x 471 hr).

§ 423.153(c) (No Change):

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

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor or MA organization offering a MA-PD plan to provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS. We estimate that it will require 942 respondents 30 minutes (0.5 hours) for a business operations specialist to provide the required material to CMS for consideration for a total annual burden of **471 hours**. The estimated annual cost is **$ 38,179** ($81.06 /hr x 471 hr).

§ 423.153(d)(1)(vii)(E) Safe Disposal of Controlled Substances for MTM Program Enrollees (New):

Under § 423.153(d), all MTM enrollees must be offered a Comprehensive Medication Review (CMR) at least annually and Targeted Medication Reviews (TMRs) no less than quarterly. A CMR is an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider that includes a review of the individual's medications and may result in the creation of a recommended medication action plan. An individualized, written summary in CMS's Standardized Format must be provided following each CMR. As previously stated, the

burden estimates for providing CMR summaries in the Standardized Format are in the Supporting Statement for CMS-10396. The SUPPORT Act expanded the population of beneficiaries that must be targeted for Part D MTM, and added a requirement that information on the safe disposal of prescription drugs that are controlled substances be furnished to all MTM program enrollees.

We estimate that in 2022 there will be 50,684,424 Part D enrollees and 10,366 of those will meet the new MTM targeting criteria as ARBs, leaving 50,674,058 Part D enrollees (50,684,424 Part D enrollees minus 10,366 enrollees meeting the ARB criteria) that must be targeted for MTM if they meet the existing criteria. Our internal data shows that 6.54 percent of Part D enrollees will be targeted for MTM programs under the existing criteria. Hence, this leaves 3,314,083 Part D enrollees (0.0654 * 50,674,058) who will be targeted for MTM under the existing criteria. Of the 3,314,083 targeted enrollees, as stated previously, based on internal CMS data, we estimate 71.8 percent will accept the annual CMR offer.

All targeted beneficiaries who have not opted out of the MTM program must receive TMRs at least quarterly, and we are allowing Part D sponsors the flexibility of choosing whether to include safe disposal information in the CMR, through a TMR or other MTM correspondence or service at least once annually. Since we assume that 71.8 percent of targeted enrollees accept an offer of a CMR, it follows that 28.2 percent (100 percent minus 71.8 percent) of Part D enrollees who are targeted for enrollment in an MTM program refuse the CMR offer but do not opt out of the MTM program completely. As discussed previously, 10,366 ARBs under the new criteria and 3,314,083 enrollees under the existing criteria, for a total of 3,324,449 enrollees (3,314,083 + 10,366) will be targeted to receive a CMR. Therefore 937,495 enrollees (3,324,449 total enrollees x 0.282 who refuse a CMR) would need to be mailed the safe disposal information as part of a TMR or other MTM correspondence or service.

We estimate a one-time burden of 2 hours at $120.64/hr for a pharmacist to develop the materials to be sent to the beneficiaries. In aggregate we estimate a one-time burden of **1,884 hours** (942 contracts x 2 hr) at a cost of **$227,286** (1,884 hr x $120.64/hr). Although there might be the need for updates in future years, these will be minor and may only occur in some future years. Hence, we are scoring this as a one-time update. The total hours and cost for this one-time burden is annualized over 3 years (**628 hours and $75,762**, respectively) and for the purposes of the summary table in section 12.3.27 of this package.

We estimate that it will take on average 2 hours at $91.96/hr for a computer programmer to upload the information into the systems. This would result in a one-time burden of **1,884 hours** (2 hr x 942 contracts) at a cost of **$173,253** (1,884 hours x $91.96/hr). Once the information is uploaded into the contract's database, we anticipate no further cost associated with this task, as the process will be automated after the initial upload with the same information on subsequent materials that are sent. The total hours and cost for this one-time burden is annualized over 3 years (**628 hours and $57,751**, respectively) for the purposes of the summary table in section 12.3.27 of this package.

The burden associated with preparing and uploading these materials had not been included in the proposed or final rules (4190-P and 4190-F2, respectively), however we include it based on

estimates for other similar provisions in those rules for which no comments were received. Thus, we believe the estimates to be an accurate assessment of burden.

We are assuming that any safe disposal information that is not included in a CMR is either i) being mailed in a TMR, which may be as short as one page and may contain private health information or ii) is mailed as a stand-alone document which does not contain any private health information. For purposes of impact, i) if one additional page is included in the TMR, then there is no additional postage; ii) if the safe disposal information is mailed separately, there would be no private health information, and the burden would be the cost of one page plus bulk postage. Due to a lack of data in regard to what percentage of safe disposal information will be mailed as a CMR, TMR, or other MTM correspondence or service, we are assuming the maximum amount, which is that all safe disposal information not sent with a CMR will be one page that is mailed separately using bulk postage. The cost to mail one page of safe disposal information is $0.01095 per enrollee if the letter does not contain private health information and thus bulk mailing is used (line 28) [1 page x $2.50 per ream of paper / 500 sheets] + [1 page x $50 per toner / 10,000 pages] + [$0.19 / 200 items]). Therefore, we estimate that the cost of mailing safe disposal information to those MTM enrollees who do not receive it in a CMR summary is **$10,266** (937,495 enrollees x $0.01095 mailing cost per page).

Table 7. Burden Summary for Safe Disposal of Controlled Substances for MTM Program Enrollees

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153(d)(1)(vii)(E)	Developing safe disposal materials	RK	942	942	2	1884	120.64	227,286	0
§ 423.153(d)(1)(vii)(E)	Programming updates for safe disposal materials	RK	942	942	2	1884	91.96	173,253	0
§ 423.153(d)(1)(vii)(E)	Mailing of safe disposal information (via TMR or other correspondence, not via CMR Standardized Format)**	TPD	942	937,495	n/a	n/a	n/a	10,266	10,266
Totals		Varies	942	939,379	Varies	3,768	Varies	410,805	10,266

*R (reporting), RK (recordkeeping), and TPD (third party disclosure)
**Non-labor requirements and costs

§ 423.153(f) Drug Management Programs ***(Revised)***

The initial DMP framework, codified in final rule 4182-F, permitted Part D plan sponsors to voluntarily establish a drug management program (DMP). Burden associated with DMPs is estimated at the parent organization level. A CMS analysis found that in 2020, 231 parent organizations included a DMP.

The requirements for DMPs are codified at § 423.153(f). The estimated reporting burden has five aspects: (1) designing a DMP, which must include written policies and procedures; (2) conducting case management, which includes sending written information about PARBs to prescribers; (3) programming and issuing written notices to PARBs and ARBs; (4) disclosing data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx; and (5) transferring case management information upon the request of a new sponsor when a PARB or ARB switches plans.

For one-time initial development, we estimate it takes each parent organization 80 hours for a team of four clinical and non-clinical staff to design its DMP. Thus the burden for one parent organization is 320 hours (80 hr x 4 staff). The aggregate burden for the 231 parent organizations to develop DMPs consistent with the requirements of §423.153(f) is **73,920 hours** (231 parent organizations x 320 hr). We estimate that the one-time development requires two pharmacists (working at $120.64/hr) and two general operation managers (working at $120.90/hr) per organization. The average hourly wage for the organization's development team is $120.77/hr [(2 pharmacists * $120.64/hr) + (2 managers * $120.90/hr) = $483.08/4 staff = $120.77/hr]. Consequently, the aggregate one-time cost to develop the DMP is **$8,927,318** ($120.77/hr * 73,920 hr).

The Part D parent organizations with DMPs have to upload beneficiary notices into their internal claims systems before they can issue them. The notices include initial notice, second notice, and alternate second notice (already submitted under the PRA package with revisions associated with the finalized rule CMS 4190-F (RIN 0938-AT97), as applicable, and submitted to OMB for approval under this collection of information request's control number or 0938-0964). We estimate that it will take each organization, on average, 5 hours at $91.96/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimated a one-time burden of **1155 hours** (5 hr * 231 sponsors) at a cost of **$106,214** (1055 hr * $91.96/hr). This burden estimate is revised from the last approved package to reflect the number of parent organizations for which DMP data is available (increased from 219 to 231).

Once the DMP is developed and in place, case management is conducted. The provisions codified at § 423.153(f) require Part D sponsors to conduct case management of potentially at-risk beneficiaries (PARBs) identified by the CMS overutilization management system (OMS) through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines. The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. Written information does not require a standardized form and may be sent electronically or faxed. Accordingly, burden for

sending this information is not accounted for separately and is assumed to be part of the overall case management burden. We estimated it would take an average of 5 hours for a sponsor to case-manage a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. We assume that 2 of the 5 hours on average would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.) at $120.64/hr, 2 hours would be conducted by a health technician ("Technician, All other") at $54.64/hr, and 1 hour would be conducted by a physician at $210.44/hr to work directly with providers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $561.00 per PARB case managed ([2 hr x $120.64/hr] + [2 hr * $54.64/hr] + [1 hr * $210.44/hr]). Therefore, the case management team's average hourly wage is $112.20/hr ($561.00 / 5 hr). CMS data from 2020 estimates that annually 21,207 PARBs will be identified based on minimum OMS criteria. In aggregate, we estimate annual burden for an estimated 21,207 enrollees annually subject to case management to be **106,035 hours** at a cost of cost **$ 11,897,127** per year (21,207 enrollees * 5 hours * 112.20/hr for the case management team).

As a result of case management, a proportion of PARBs receive notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Approximately 5 percent of PARBs identified by minimum OMS criteria receive an initial and second notice (or alternate second notice). Therefore, it follows that approximately 1,060 (21,207 * 0.05) PARBs overall will receive initial and second notice (or alternate second notice) annually. We estimate it takes 5 minutes (0.0833 hr) at $54.64/hr for a health technician to send each notice for a total burden of 0.1667 hr per enrollee. In aggregate, we estimate an annual burden of **177 hours** (1,060 enrollees * 0.1667 hr) at a cost of **$9,655** (177 hr * $54.64/hr) to be attributed to notice requirements. This is a reduction in burden estimated in the currently-approved version of this package based on more current data on rates of notice being sent to PARBs. The initial notice, second notice, and alternate second notice have been submitted as attachments to this PRA package, with revisions associated with finalized rule CMS 4190-F (RIN 0938-AT97) for OMB approval under this collection of information request's control number or 0938-0964.

With respect to the burden of disclosure of DMP data to CMS based on the outcome of case management of PARBs, we estimate it takes sponsors on average 1 minute (0.0167 hr) at $54.64/hr for a health technician to document the outcome of case management and any applicable coverage limitations in OMS and/or MARx. In aggregate, we estimate an annual burden of **354 hours** (21,207 PARBs * 0.0167 hr) at a cost of $19,351 (354 hr * $54.64/hr).

Consistent with § 423.153(f)(15)(ii)(E), plan sponsors are required to transfer case management information upon the request of a new sponsor when a PARB or ARB switches plans. CMS provides a sample transfer memo that sponsors may use to transfer such information (see attachment 6f). According to internal CMS data for the first quarter of 2020, 11 beneficiaries switched plans. We estimate it takes sponsors on average 1 hour at $54.64/hr for a health technician to assemble and send the requested documents for each beneficiary identified in the DMP who transfers plans. Therefore, we estimate an annual burden of **$601** (11 beneficiaries * 1 hr * $54.64/hr) to complete information transfer requests.

For the purposes of the summary table in section 12.3.27, one-time burden is annualized over the 3 year period of approval.

Table 8. Burden Summary for DMP New, Non-rule-related ICRs and Revised, Existing ICRs

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153	Create DMP (new, non-rule)	RK	231	231	320	73,920	120.77	8,927,318	0
§ 423.153	Upload Notices (revised)	RK	231	231	5	1155	91.96	106,214	0
§ 423.153	Conduct Case Management (new, non-rule)	RK	231	21,207	5	106,035	112.2	11,897,127	11,897,127
§ 423.153	Send Notices (revised)	TPD	231	1,060	0.1667	177	54.64	9,655	9,655
§ 423.153	Report to CMS (new, non-rule)	R	231	21,207	0.0167	354	54.64	19,351	19,351
§ 423.153	Transfer of Case Management (new, non-rule)	TPD	11	11	1	11	54.64	601	601
	Subtotal	*N/A*	*231*	*43,947*	*varies*	*181,652*	*varies*	*20,960,226*	*11,926,734*

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

*Mandatory Drug Management Programs **(New, per 4190-F2)***

Although voluntary under section 704 of CARA, as described in the background and justification sections of this document, a CMS analysis found that in 2019 a majority of Part D contracts (669 of 779, or 85.9 percent) included a DMP. As of January 1, 2022, DMPs will be mandatory. Therefore, this section outlines the burden for with Part D sponsors who did not voluntarily establish DMPs. Final rule 4190-F2 included burden based on 2019 DMP data. As of this package revision, 2020 data is available. Thus, burden estimates in this package are being updated to reflect 2020 data rather than the 2019 data which was included in the final rule. We estimate burden at the parent organization level, because we believe that is a closer reflection of the number of systems to be updated versus the contract level. The 2020 contracts without DMPs are run by 78 parent organizations.

For one-time initial development, we estimate it would take each parent organization without a DMP 80 hours for a team of four clinical and non-clinical staff to design its DMP. Thus the burden for one parent organization is 320 hours (80 hr x 4 staff). Therefore, the aggregate burden for the 79 remaining parent organizations to develop DMPs consistent with the

requirements of §423.153(f) is **24,960 hours** (78 parent organizations x 320 hr).

With regard to costs, we estimate that development, will require a development team consisting of four staff, two pharmacists (working at $120.64/hr) and two general operation managers (working at $120.90/hr) per organization. The average hourly wage for the organization's development team is $120.77/hr [(2 pharmacists * $120.64/hr) + (2 managers * $120.90/hr) = $483.08/4 staff = $120.77/hr]. Consequently, the aggregate cost to develop the DMPs is **$3,014,419** ($120.77/hr * 24,960 hr).

The contracts run by the parent organizations that did not voluntarily establish a DMP are generally smaller plans that in some cases offered alternative means of managing comprehensive beneficiary care, such as through PACE. Accordingly, based on 2020 OMS report data, we found that only 157beneficiaries who met the minimum OMS criteria were not reported in 2020 by CMS to the sponsors, because the sponsors did not have a DMP. This represents the additional number of PARBs that will be added to the total burden when DMPs become mandatory.

Once required DMP policies are developed and operational, sponsors would have to case-manage their PARBs (as outlined in § 423.153(f)(2)). The case management requirement includes a requirement that sponsors send written information to prescribers about PARBs. Written information does not require a standardized form and may be sent electronically or faxed. Accordingly, burden for sending this information is not accounted for separately and is assumed to be part of the overall case management burden. We estimated it would take an average of 5 hours for a sponsor to case-manage a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. We assume that 2 of the 5 hours on average would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.) at $120.64/hr, 2 hours would be conducted by a health technician ("Technician, All other") at $52.64/hr, and 1 hour would be conducted by a physician at $210.44/hr to work directly with providers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $561.00 per PARB case managed ([2 hr x $120.64/hr] + [2 hr * $54.64/hr] + [1 hr * $210.44/hr]). Therefore, the case management team's wage is $112.20/hr ($561.00 / 5 hr). In aggregate, we estimate an annual burden of **785 hours** (5 hr x 157 beneficiaries at a cost of **$88,077** per year (785 hr x $112.20/hr).

The 78 Part D parent organizations affected by this requirement also will have to upload beneficiary notices into their internal claims systems before they can issue them. We estimate that it will take each organization, on average, 5 hours at $91.96/hr for a computer programmer to upload all of the notices into their claims systems (note, this is an estimate to upload all of the documents in total, not per document). In aggregate, we estimated a one-time burden of 390 hours (5 hr * 78 sponsors) at a cost of $35,864 (390 hr * $91.96/hr).

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimate that 8 beneficiaries (157 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). At most, 8 parent organizations would be responsible for sending the notices to these 8 beneficiaries. CMS estimates it will take 10 minutes (0.1667 hr) at $54.64/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden for sending notices to

beneficiaries of 1.3336 hours (8 beneficiaries x 0.1667 hr) at a cost of $73 (1.3336 hr x $54.64/hr).

As to disclosure of DMP case management outcomes data to CMS pursuant to § 423.153(f)(15), the parent organizations newly impacted by a mandatory DMP policy will be required to report to CMS the outcome of case management via OMS and any associated coverage limitation information into MARx. We estimate that it would take parent organizations on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of **2.6219 hours** (157 newly identified PARBs annually * 0.0167 hr) at a cost of $143 (2.6219 hr * $54.64/hr).

Consistent with § 423.153(f)(15)(ii)(E), plan sponsors are required to transfer case management information upon the request of a new sponsor when a PARB or ARB switches plans. Burden associated with the transfer of information is located in the prior section titled "*Drug Management Programs*" as a non-rule related burden addition. As the number of beneficiaries switching plans was 11 beneficiaries out of 21,207 for 2020, the relative proportion of the 158 beneficiaries within parent organizations without DMPs who may switch plans is negligible.

For the purposes of the summary table in section 12.3.27, one-time burden is annualized over the 3 year period of approval.

Table 9. Burden Summary for Mandatory DMPs

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.153	Create DMP (rule, 4190-F2)	RK	78	78	320	24,960	120.77	3,014,419	0
§ 423.153	Upload Notices (rule, 4190-F2)	RK	78	78	5	390	91.96	35,864	0
§ 423.153	Conduct Case Management (rule, 4190-F2)	RK	78	157	5	785	112.2	88,077	88,077
§ 423.153	Send Notices (rule, 4190-F2)	TPD	8	8	0.1667	1.3336	54.64	73	73
§ 423.153	Report to CMS (rule, 4190-F2)	R	78	157	0.0167	2.6219	54.64	143	143
	Subtotal	*N/A*	*78*	*478*	*varies*	*26,138*	*varies*	*3,138,576*	*88,293*

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

Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs ***(New, per 4190-F2)***

The updated clinical guideline criteria to incorporate history of opioid-related overdose increase the total number of beneficiaries identified and included in DMPs. The estimates that follow outline the burden associated with these additional PARBs. Final rule 4190-F2 included burden

based on 2019 DMP data. As of this package revision, 2020 data is available. Thus, burden estimates in this package are being updated to reflect 2020 data rather than the 2019 data which was included in the final rule. We estimate burden at the parent organization level, because we believe that is a closer reflection of the number of systems to be updated versus the contract level. In 2020, Part D contracts were represented by a total of 309 parent organizations. The estimates are inclusive of the 78 parent organizations who have not yet developed DMPs because when the requirement to include beneficiaries with a history of opioid-related overdose in DMPs takes effect January 1, 2022, DMPs will be mandatory for all Part D sponsors.

In producing the estimates below, the burden per affected enrollee for case management (5 hr/response), notification of enrollees (10 min/response), and report to CMS (1 min/response) are identical with those estimated in the previous section (Mandatory Drug Management Programs).

Model beneficiary notices provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, will need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal. CMS estimates it will take no more than 1 hour at $54.64/hr for a pharmacy technician to draft and implement such changes. In aggregate, CMS estimates a one-time burden of **309 hours** (309 parent organizations x 1 hr/response) at a cost of **$16,884** (309 hr x $54.64/hr).

CMS's internal analysis based on methodology in final rule 4190-F2, estimates that in 2020, 14,407 enrollees met the criteria of an opioid-related overdose and would be PARBs. All of these PARBs will require case management. Using the wage and cost data outlined for the case management team in aggregate, CMS estimates an annual burden of **72,035 hours** (5 hr x 14,407 PARBs) at a cost of $8,082,327 (72,035 hr x $112.20/hr).

CMS estimates that about 47.5 percent or 6,843 beneficiaries (14,407 beneficiaries x 0.475) of this population will receive an initial notice from the plan sponsor, informing the beneficiary of the sponsor's intention to limit their access to coverage of opioids and/or benzodiazepines. Thus, the beneficiary will also receive a second or alternate second notice informing them whether the limitation was in fact implemented. CMS estimates it will take 10 minutes (0.1667 hr) at $54.64/hr for a pharmacy technician to send two notices (each notice would require 5 minutes). In aggregate, CMS estimates an annual burden of **1,141 hours** (6,843 enrollees x 0.1667 hr) at a cost of **$ 62,329** (hr x $54.64/hr).

With respect to the reporting of DMP data to CMS for PARBs identified based on history of opioid-related overdose, CMS estimates it will take sponsors (on average) 1 minute (0.0167 hr) at $54.64/ hr for a pharmacy technician to report in OMS and/or MARx the outcome of case management and any applicable coverage limitations. In aggregate, CMS estimates an annual burden of **241 hours** (14,407 PARBs × 0.0167 hr) at a cost of **$13,146** (241 hr × $54.64/hr).

For the purposes of the summary table in section 12.3.27, one-time burden is annualized over the 3 year period of approval.

Table 10. Burden Summary for Beneficiaries with History of Opioid-Related Overdose Included in DMPs

Regulatory Citation	Provision Brief Title	Response Type *	# of Respondents	# of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§423.153	Revise Notices (rule, 4190-F2)	RK	309	309	1	309	54.64	16,884	0
§ 423.153	Conduct Case Management (rule, 4190-F2)	RK	309	14,407	5	72,035	112.2	8,082,327	8,082,327
§ 423.153	Send Notices (rule, 4190-F2)	TPD	309	6,843	0.1667	1,141	54.64	62,329	62,329
§ 423.153	Report to CMS (rule, 4190-F2)	R	309	14,407	0.0167	241	54.64	13,146	13,146
	Subtotal	*N/A*	*309*	*35,966*	*varies*	*73,726*	*varies*	8,174,686	8,157,802

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

Drug Management Program Burden Summary (Rule and Non-Rule Related Revisions)

In summary, the total burden and cost for DMPs associated with both non-rule-related changes and 4190-F2-related changes (from Tables 8, 9, and 10) is totaled in the following table. One-time burden has been annualized over the 3 year approval period of this package.

Table 11. DMP Burden and Cost Summary for Rule and Non-Rule Related Revisions (§423.153(f))

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Create DMP **	RK	309	103**	320	32,960**	120.77	3,980,579**
§ 423.153	Revise Notices**	RK	309	103**	1	103**	54.64	5,628**
§ 423.153	Upload Notices**	RK	309	103**	5	515**	91.96	47,359**
§ 423.153	Conduct Case Management	RK	309	35,771	5	178,855	112.20	20,067,531

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Send Notices	TPD	309	7,911	0.1667	1,319	54.64	72,057
§ 423.153	Transfer of Case Management	TPD	11	11	1	11	54.64	601
§ 423.153	Report to CMS	R	309	35,771	0.0167	597	54.64	32,641
	Subtotal	*N/A*	*309*	*79,773*	*varies*	*214,360*	*Varies*	*24,206,396*

*R (reporting), TPD (third-party disclosure), RK (recordkeeping)
**One-time burden and cost annualized over 3 years

12.3.12 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 **$11,673** ($81.06 /hr x 144 hrs).

12.3.13 Determination of payment (§ 423.329) (No change)

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 66 stand-alone Part D plan contracts and 139 PACE contracts (for a total of 205

respondents) 52 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **10,660 hours**. The estimated annual cost is **$864,100** ($81.06 /hr x 10,660 hr).

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

The burden associated with this requirement is the time and effort necessary for MA organizations submit the required claims data to CMS. We estimate that on an annual basis it will take 876 MA-PD contracts 15 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **13,140 hours**. The estimated annual cost is **$1,065,128** ($81.06 /hr x 13,140 hr).

12.3.14 Risk sharing arrangements (§ 423.336) (No change)

(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 **$8,106** ($81.06 /hr x 100 hr).

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required cost data to CMS. We estimate that on an annual basis it will take each of the 942 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 **113,040 hours (942 sponsors x 10 hours x 12 submissions per year)**. The estimated annual cost is **$9,163,022** ($81.06 /hr x 113,040hr).

12.3.15 Retroactive adjustments and reconciliations (§ 423.343) (No change)

(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 942 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,420 hours**. The estimated annual

cost is **$763,585** ($81.06 /hr x 9,420hr).

(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 942 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,420 hours**. The estimated annual cost is **$763,585** ($81.06/hr x 9,420 hr).

12.3.16 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.

12.3.17 Contract provisions (§ 423.505) (No change)

(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 942 respondents 52 hours for a business operations specialist to maintain the required documentation on an annual basis, for total annual burden of **48,984** hours. The estimated annual cost is **$3,970,643** ($81.06 /hr x 48,9846 hr).

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

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to submit the required certified data to CMS. We estimate that on an annual basis it will take 942 respondents 8 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **7,536 hours**. The estimated annual cost is **$610,868** ($81.06 /hr x 7,536hr).

12.3.18 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..

12.3.19 General Provisions (§ 423.562) (No change)

(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 608 Part D plan sponsors to disclose the necessary information to enrollees. We estimate that it will require each of the 942 Part D plan sponsors 8 hours for a business operations specialist to disclose the information for a total annual burden of **7,536 hours**. The estimated annual cost is **$610,868** ($81.06 /hr x 7,536 hr).

12.3.20 Grievance procedures (§ 423.564) (No change)

(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 942 Part D plan sponsors will provide notification of a total of 132,000 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 13,200 grievances and oral notification in 118,800 grievances. We estimate it will take 30 minutes (0.5 hours) to provide written notification for a total annual burden of **6,600 hours**. We estimate it will take 15 minutes (0.25 hours) for a business operations specialist to provide oral notification to enrollees for a total annual burden of **29,700 hours**. The total number of hours is **36,300** (6,600 + 29,700) annually. The estimated annual cost is **$2,942,478** ($81.06 /hr x 36,300 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 942 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 **48,984 hours**. The estimated annual cost is **$3,970,643** ($81.06 /hr x 48,984 hr).

12.3.21 Standard timeframe and notice requirements for coverage determinations (§ 423.568) (No change)

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to document oral requests and retain the documentation in the case file. We estimate that Part D plan sponsors will receive about 3,675,000 standard coverage determination requests annually and, of that number, 1,837,500 will be oral requests. We estimate that it will take a Part D plan sponsor 3 minutes (0.05 hours) for a business operations specialist to document and retain the required documentation in the case file. Thus, we estimate that it will take 942 Part D plan sponsors a total of **91,875 hours** to perform this function on an annual basis. The estimated annual cost is **$ 7,447,388** ($81.06 /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, the physician's or other prescriber's supporting statement. For payment requests, the plan sponsor must notify the enrollee of its decision and make any applicable payment no later than 14 calendar days after receiving the request.

The burden associated with this requirement is the time and effort necessary for the 942 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 $**74,473,956** ($81.06 /hr x 918,751 hr).

12.3.22 Expediting certain coverage determinations (§ 423.570) (No change)

(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 942 Part D plan sponsors **58,188 hours** to perform this function on an annual basis. The estimated annual cost is **$4,716,679** ($81.06 / 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 942 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 **$248,287** ($81.06 /hr x 3,063 hr).

12.3.23 Timeframes and notice requirements for expedited coverage determinations (§ 423.572) (No change)

(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 942 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 **$24,576,419** ($81.06 /hr x 303,188 hr).

12.3.24 Exceptions process (§ 423.578) (No change)

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 **$125,672,243** ($210.44/hr x 597,188 hr).

12.3.25 Administration of subsidy program (§ 423.800) (No change)

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 942 respondents approximately 52 hours for a business operations specialist to provide the information to CMS for a total of **48,984 hours** annually. The estimated annual cost is **$3,970,643** ($81.06/hr x 48,984 hr).

We also estimate that it will take approximately 26 hours for each of the 942 respondents to maintain the information for tracking purposes for a total of **24,294 hours** annually. The estimated annual cost is **$1,985,322** ($81.06/hr x 24,294 hr).

12.3.26 Change in Ownership (§ 423.892) (No change)

(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 9 entities (1 percent of 942) about 1 hour for a business operations specialist to submit the required notification to CMS, for a total of approximately **9 hours**. The estimated annual cost is $730 ($81.06 /hr x 9 hr).

12.3.27 Burden Summary

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

CFR Section	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
423.36(b)	R	942	0.017	2,021	1,903,752	32,364	2,623,408
			1	1	942	942	76,359
423.38(c)	R	50	0.083	37,350	1,867,519	155,627	12,615,091
423.44(b)	R	942	0.083	527	496,344	41,197	3,339,393
423.46(b)	R	942	0.25	4,197	3,954,000	988,500	80,127,810
423.48	R	942	2	1	942	1,884	152,717
423.104(g)	R	942	10	1	942	9,420	763,585
423.153(b)	R	942	0.5	1	942	471	38,179
423.153(c)	R	942	0.5	1	942	471	38,179

423.153(f)	R	309	0.0167	116	35,771	597	32,641
423.168(c) 423.171(a) 423.904(a)	R	12	1	12	144	144	11,673
423.329(b)	R	205	52	1	205	10,660	864,100
		876	15	1	876	13,140	1,065,128
423.336(a)	R	5	20	1	5	100	8,106
423.336(c)	R	942	10	12	11,304	113,040	9,163,022
423.343(c)	R	942	10	1	942	9,420	763,585
423.343(d)	R	942	10	1	942	9,420	763,585
423.505(f)	R	942	8	1	942	7,536	610,868
423.800(b)	R	942	52	1	942	48,984	3,970,643
423.892(c)	R	9	1	1	9	9	730
Subtotal (Reporting)		***942***	***varies***	***varies***	***8,278,407***	***1,443,925***	***117,028,802***
423.46(d)	RK	942	0.083	4,197	3,954,000	328,182	26,602,433
423.120(b)	RK	942	2	1	942	1,884	152,717
423.120(d)	RK	876	1	1	876	876	71,009
423.128(a)	RK	942	80	1	942	75360	6,108,682
423.128(b)(11)	RK	308	2	1	103**	205**	24,771**
			2	1	103**	205**	18,882**
423.153(d)(1)(vii)(E)	RK	942	2	1	314**	628**	75,762**
			2	1	314**	628**	57,751**
423.153(f)	RK	309	320	1	103**	32,960**	3,980,579**
			1	1	103**	103**	5,628**
			5	1	103**	515**	47,359**
			5	116	35,771	178,855	20,067,531
423.505(d)	RK	942	52	1	942	48,984	3,970,643
423.564(g)	RK	942	52	1	942	48,984	3,970,643
423.568(a)(3)	RK	942	0.05	1,951	1,837,500	91,875	7,447,388
423.570(c)(2)	RK	942	0.05	1,235	1,163,750	58,188	4,716,679
423.570(d)	RK	942	0.25	13	12,250	3,063	248,246
423.800(b)	RK	942	26	1	942	24,492	1,985,322
Subtotal (Record keeping)		***942***	***Varies***	***Varies***	***7,009,999***	***895,987***	***79,552,024***
423.34(e)	TPD	942	0.25	138	130,000	32,500	2,634,450
423.44(b)	TPD	942	1	1	942	942	76,359
			0.017	527	496,344	8,438	683,972
			1	1	942	942	76,359
			0.017	1	1,100	18.7	1,516
			1	1	942	942	76,359
			0.1	19	17,772	1,777	144,044
423.120(b)	TPD	942	40	1	942	37,680	3,054,341
			0.083	20,170	19,000,000	1,577,000	127,831,620
423.128(a)	TPD	942	120	1	942	113,040	9,163,022

423.128(b)(11)	TPD	308	n/a	118,333	36,446,413	n/a	399,088
423.128(e)	TPD	942	160	1	942	150,720	12,217,363
423.128(e)(5)	TPD	308	n/a	1,893,320	583,142,604	n/a	5,853,585
423.153(d)(1)(vii)(E)	TPD	942	n/a	995	937,495	n/a	10,266
423.153(f)	TPD	309	0.1667	4.3	7,911	1,319	72,057
			1	1	11	11	601
423.562(a)	TPD	942	8	1	942	7,536	610,868
423.564(e)	TPD	942	0.5	14	13,200	6,600	534,996
			0.25	126	118,800	29,700	2,407,482
423.568(b), (c), (d), and (f)	TPD	942	0.25	1,209	1,139,250	284,813	23,086,942
			0.25	2,692	2,535,750	633,938	51,387,014
423.572(a) and (c)	TPD	942	0.25	1,287	1,212,750	303,188	24,576,419
423.578	TPD	n/a	0.25	n/a	2,388,750	597,188	125,672,243
Subtotal (Third Party Disclosure)		***942***	***Varies***	***Varies***	***647,594,744***	***3,788,292***	***390,570,965***
TOTAL (R, RK, and TPD)		***942***	***Varies***	***Varies***	***662,883,150***	***6,128,204***	***587,151,791***

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

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

12.4.1 Eligibility determinations for low-income subsidies (§ 423.904) (No change)

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 **$472,097** (6,120 hr x $77.14 /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 **$78,683** (1,020 hr x $77.14 /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.

12.4.2 Requirements (§ 423.910) (No change)

(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 **$472,097** ($77.14 /hr x 6,120 hr).

12.4.3 Burden Summary

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

CFR Section	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	472,097
	R		20	1	51	1,020	78,683
423.910(d)	R	51	10/month	12	51	6,120	472,097
Subtotal		**51**	**Varies**	**varies**	**600,102**	**13,260**	**1,022,876**

*R (reporting).

12.5 ICRs Regarding the Part D Sponsor's System Programming (§ 423.120(c)(6)) **(*Removed, see section 15 of this Supporting Statement for details*)**

12.6 ICRs Regarding the Creation of Precluded Provider Model Notices to Medicare Beneficiaries and Prescribers (§ 423.120(c)(6)) ***(Removed, see section 15 of this Supporting Statement for details)***

12.7 ICRs Regarding the Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6)) ***(Revised)***

For this provision we estimate that it will take an average of 5 minutes (0.083 hr) at $43.34/hour for an insurance claim and policy processing clerk to generate and disseminate the aforementioned notice.

In 2020 and 2021, we estimate that roughly 150 prescribers will be added to the Preclusion List, though this will be largely offset by the same number of prescribers being updated to reflect a change in their preclusion status (for example, based on reenrollment after the expiration of a reenrollment bar) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of **1,245 hours** (15,000 beneficiaries x 0.083 hr) at a cost of **$53,958** (1,245 hr x $43.34 /hr) or $360 per prescriber ($53,958/150 prescribers).

Table 14. Precluded Provider Model Notices Burden and Cost Summary (Private Sector: Subtotal)

CFR Section	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (hr, all respondents)	Total Annual Cost ($)
423.120(c)(6)	TPD	150	0.083 (5 min)	Varies	15,000	1,245	53,958
Subtotal		**150**	0.083 (5 min)	**Varies**	**15,000**	**1,245**	53,958

*TPD (third party disclosure).

SUMMARY OF REQUIREMENTS AND ANNUAL BURDEN AND COST ESTIMATES

Table 15 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. Business Continuity Plans (Revised), from Table 2	14	Varies	1	14	2,360	191,302
12.3. Medicare Prescription Drug Benefit Program: Plans (Revised), from Table 12	942	Varies	Varies	662,883,150	6,128,204	587,151,791
12.7 Preparation and issuance of Precluded Provider model notices (Revised), from Table 14	150	0.083	Varies	15,000	1,245	53,958
Subtotal (Private Sector)	*942*	*Varies*	*Varies*	*662,898,164*	*6,131,809*	*587,397,051*
12.2. Medicare Prescription Drug Benefit Program: Bene (Revised), from Table 3	3,315,100	Varies	1	3,315,100	828,775	22,434,939
Subtotal (Individuals and Households)	*3,315,100*	*Varies*	*1*	*3,315,100*	*828,775*	*22,434,939*
12.4. State Eligibility Determinations (No Change), from Table 13	51	Varies	Varies	600,102	13,260	1,022,876
Subtotal (States)	*51*	*Varies*	*Varies*	*600,102*	*13,260*	1,022,876
TOTAL	**3,316,093**	**Varies**	**Varies**	**666,813,366**	**6,973,844**	**610,854,866**

INFORMATION COLLECTION INSTRUMENTS, INSTRUCTIONS AND GUIDANCE DOCUMENTS

Attachments 1a – 1f – Drug Management Program Standardized Notices and Model Letters (Adds new documents, attachments 1e and 1f)
(See section 12.3.11 Drug Utilization Management, Quality Assurance, Medication Therapy Management (MTM), and Drug Management Programs)

1a – Instructions for Drug Management Program Notices (Revised)
1a – Crosswalk for Instructions for Drug Management Program Notices

1b – Initial Notice Sent to Potentially At-Risk Beneficiaries (Revised)
1b – Crosswalk for Initial Drug Management Program Notice

1c – Second Notice Sent to Beneficiary Designating At-Risk Status (Revised)
1c – Crosswalk for Second Drug Management Program Notice

1d – Alternate Second Notice Sent to Beneficiary Not Considered At-Risk (Revised)
1d – Crosswalk for Alternate Second Drug Management Program Notice

1e – Model Prescriber Inquiry Letter (New)
1e – 60-Day Crosswalk for Model Prescriber Inquiry Letter

1f – Model Sponsor Information Transfer Memo (New)
1f – 60-Day Crosswalk for Model Sponsor Information Transfer Memo

Attachment 2 – Model Precluded Provider Letter (Revised)
(See section 12.7, Preparation and Issuance of Model Notices)
Attachment 2 – Crosswalk for Model Precluded Provider Letter

Attachment 3a-h) – Part D Explanation of Benefits (Revised)
(See section 12.3.10, Medicare Prescription Drug Benefit Program: Plans, Dissemination of Plan Information)

3 - Crosswalk for EOB and Exhibits
3a - 2022 Model Part D Explanation of Benefits (All Sections Included)
3b - Exhibit A: Example Cover Page of the Model Part D EOB
3c - Exhibit B: Examples of Section 1 (the List of Prescriptions)
3d - Exhibit C: Example of Section 2 (Drug Payment Stages)
3e - Exhibit D: Example of Section 3 (Amounts and Definitions for TrOOP and Total Drug Costs)
3f - Exhibit E: Example of Section 4 (Changes to the Formulary)
3g - Exhibit F: Example of Sections 5 and 6 (Information for Reference)
3h - Exhibit G: Example of a Part D EOB (All Sections Included)

Crosswalks reflect additional minor revisions based on comments received during the 60-day comment period. None of these revisions change burden estimates in section 15.

12B. Information Collection Requests Exempt From the Paperwork Reduction Act
(No Change)

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.).

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.
PRA.

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 0938-1378).

Business Continuity Plans (§§ 422.504(o) and 423.505 (p)). Burden associated with these requirements is submitted under CMS-10260 (OMB 0938-1051).

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 $778. This is based upon the 2021 Washington-Baltimore-Northern VA Locality Pay Area hourly rate for a GS-11/step 6 of $38.90/hr (https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2021/DCB_h.pdf) multiplied by the number of burden hours (20).

15. Changes to Burden

This 2021 collection of information request seeks to extend the November 30, 2021, expiration date for three years as it is associated with two final rules and with 60- and 30-day Federal Register notices that provided the public with additional time to review and comment.

15.1 Non-rule Changes: Deletions

15.1.1 Business Continuity Plans (§§ 422.504(o) and 423.505 (p))

Attachments related to business continuity plans are being removed from this package. Specifically, the attachments being removed are:

Compensation Certification to be Completed by All Organizations
Compensation Certification to be Completed by Any Organization with Renewal Commission
Compensation Structure for Plans
Compensation Structure for Writing Agents
Covered Agent Information Sheet
Compensation Structure for Writing Agents by Contract/PBP Number
Instructions for MA and PDP Organizations
Instructions for Writing Agents
Compensation Workbook

This does not impact burden to this ICR and had been a clerical oversight. The supporting statement for this package submitted in 2015 had stated "We are also correcting the iteration that was approved by OMB on February 6, 2014 (ICR ref # 201312-0938-021) by removing Attachments 1a and 1b; 2a and 2b; 3; 4; and 5a, 5b, and 5c. All of the attachments should have been removed since the marketing requirements had been moved to a separate PRA package. This 2015 iteration does not propose any marketing-related burden adjustments since the associated burden was removed from this package and was accounted for and approved in OMB #0938-1051."

The remaining attachments relevant to this package have been renumbered as follows:

1a – Compensation Certification to be Completed by All Organizations **(Removed)**
1b – Compensation Certification to be Completed by Any Organization with Renewal Commission **(Removed)**
2a – Compensation Structure for Plans **(Removed)**
2b – Compensation Structure for Writing Agents **(Removed)**
3 – Covered Agent Information Sheet **(Removed)**
4 - Compensation Structure for Writing Agents by Contract/PBP Number **(Removed)**
5a – Instructions for MA and PDP Organizations **(Removed)**
5b – Instructions for Writing Agents **(Removed)**
5c – Compensation Workbook **(Removed)**
6a→**1a** – Instructions for Drug Management Program Notices
6b→**1b** – Initial Notice Sent to Potentially At-Risk Beneficiaries
6c→**1c** – Second Notice Sent to Beneficiary Designating At-Risk Status
6d→**1d** – Alternate Second Notice Sent to Beneficiary Not Considered At-Risk
1e – Model Prescriber Inquiry Letter **(New)**
1f – Model Sponsor Information Transfer Memo **(New)**
7→**2** – Model Precluded Provider Letter
8a→**3a** - 2022 Model Part D Explanation of Benefits (All Sections Included)
8b→**3b** - Exhibit A: Example Cover Page of the Model Part D EOB
8c→**3c** - Exhibit B: Examples of Section 1 (the List of Prescriptions)
8d→**3d** - Exhibit C: Example of Section 2 (Drug Payment Stages)
8e→**3e** - Exhibit D: Example of Section 3 (Amounts and Definitions for TrOOP and Total Drug Costs)
8f→**3f** - Exhibit E: Example of Section 4 (Changes to the Formulary)
8g→**3g** - Exhibit F: Example of Sections 5 and 6 (Information for Reference)
8j→**3h** - Exhibit G: Example of a Part D EOB (All Sections Included)

15.1.2 Enrollment Process (§ 423.32)

ICRs related to the Enrollment Process requirements at § 423.32 were removed from this package as they are accounted for in a separate PRA package (10718). This is a clerical update as the burden to the program still exists but is accounted for elsewhere. The burden estimates that had been approved as of the last-approved version of this package are listed in the summary Table 23 below. Estimates included a total of 3.954 million individuals who may newly enroll in

or change their PDP annually. This burden was calculated to be **1,975,000 hours** (3,954,000 million enrollments x 0.5 hours) for an annual cost of **$53,463,250** (1,975,000 hr x $27.07/hr individual wage). Additionally this ICR included the estimate that 2.6 million beneficiaries would need 1 minute (0.017 hours) to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of **44,200 hours** (2,600,000 million beneficiaries x 0.017 hr) and an annual cost of **$1,196,494** (44,200 hr x $27.07/hr individual wage).

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

First year estimates, which were for 2016, were removed from the ICR in section 12.1. This was an estimate for 28 entities who did not have the plans in place and took 240 hours each to fulfill the business continuity requirements, for a total burden of **6,720 hours** (28 plans x 240 hr) at a cost of $544,723 (6,720 hr x $81.06/hr for a business operations specialist). There were also an estimated 57 entities with existing plans that needed to be updated and took 120 hours to revise their business continuity plans in the first year, for a total burden of **6,840 hours** (57 x 120 hr) at a cost of **$554,450** (6,840 hr x $81.06/hr for a business operations specialist).

Table 16: One-Time Burden Removal for Business Continuity Plans

CFR Section	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	28	240	1	28	6,720	544,723
		57	120	1	57	6,840	554,450
Subtotal		**85**	**Varies**	**1**	**85**	**13,560**	**1,099,173**

15.1.4 Part D Sponsor's System Programming (§ 423.120(c)(6))

One-time burden already accounted for in the last-approved 2019 package was removed for this ICR. Using previously approved estimates of 3 full-time Software Developers and Programmers updated to 2020 wages of $109.88/hr amounts to **93,600 hours** (3 workers x 1,040 hr x 30 sponsors) at a cost of **$ 10,284,768** (93,600 hr x $ 109.88/hr) for 2019.

15.1.5 Creation of Precluded Provider Model Notices to Medicare Beneficiaries and Prescribers (§ 423.120(c)(6))

One-time burden already accounted for in the previously-approved 2019 package was removed. The one-time burden was estimated to be **636 hours** (212 organizations x 3 hr) at a cost of **$ 54,554** (636 hr x $ 81.06/hr) updated to 2020 wages for a business operations specialist.

15.1.6 Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6))

One-time burden from already accounted for in the previously approved 2019 package has been removed. Burden was disproportionately high in 2019 for the first year of implementation relative to recurring annual burden. Recurring annual burden is still reflected in the current package, only 2019 burden has been removed. For 2019 it was estimated that approximately 800 prescribers will be on the Preclusion List approximately 80,000 Part D beneficiaries affected. In aggregate, 2019 burden was estimated to be **6,640 hours** (0.083 hr/response x 80,000 responses) at a cost of **$ 287,778** (6,640 hr x $ 43.34/hr) updated to 2020 wages for an insurance claim and policy processing clerk.

15.1.7 Furnishing EOB to Enrollees (§ 423.128(e)(5))

One-time burden associated with initial system updates was already accounted for in the previously approved package and is removed from this revision. The one-time burden estimate for updating systems was 47,200 hours (160 hr per response x 295 responses) at a cost of $5,186,226 (47,200 hr x $109.88/hr) updated to 2020 waged for software developers. This was annualized over the course of OMB's anticipated 3-year approval period, for an estimated annual burden of **15,733 hours** (47,200 hr/3 years) at a cost of **$1,728,742** ($5,186,226/3 years).

15.2 Non-rule Changes: Additions and Revisions

15.2.1 Drug Management Programs (§ 423.153(f))

The purpose of this revision is to quantify burden that had previously not been separately accounted for related to the adoption of DMPs by Part D sponsors. The information collection request associated with CMS-4182-F included burden for the DMP provisions, as described in section 12.3.11. Provisions that codified existing guidance and Part D sponsor practice, were not separately accounted for at that time. Thus, new ICRs were added to this package related to sponsors who voluntarily established DMPs. This includes burden associated with developing the DMP, conducting case management, required reporting back to CMS on the outcomes of case management (in OMS) or coverage limitations (in MARx), and the burden associated with transfer of beneficiary information between sponsors when a PARB or ARB switches Part D plans.

Revised ICRs related to sponsors who had voluntarily established DMPs included burden associated with uploading DMP notices reflecting an increase in parent organizations in 2020 compared with 2017 (219 vs. 308), hourly wage associated with notices being sent by a pharmacy technician and not insurance claim specialist, and annual number of notices sent increasing from 923 to 1,060 based on the most current data. One-time (first-year only) costs were annualized over 3 years for the purposes of calculating total annual burden for the package.

Table 17. Burden Summary for DMP New, Non-rule-related ICRs and Revised ICRs

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Create DMP (new, non-rule)	RK	231	77**	320	24,640**	120.77	2,975,337**
§ 423.153	Upload Notices (revised)	RK	231	77**	5	385**	91.96	35,405**
§ 423.153	Conduct Case Management (new, non-rule)	RK	231	21,207	5	106,035	112.2	11,897,127
§ 423.153	Send Notices (revised)	TPD	231	1,060	0.1667	177	54.64	9,655
§ 423.153	Report to CMS (new, non-rule)	R	231	21,207	0.0167	354	54.64	19,351
§ 423.153	Transfer of Case Management (new, non-rule)	TPD	11	11	1	11	54.64	601
	Subtotal	*varies*	*231*	*43,693*	*varies*	*151,602*	*varies*	*14,937,911*

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

15.3 Final Rule (CMS-4190-F1 and F2) Changes

The changes to this package are located in section 12.3 of this supporting statement. The changes to burden are summarized below and are in the final count. One-time (first-year only) costs were annualized over 3 years for the purposes of calculating total annual burden for the package

15.3.1 Special Election Periods (SEPs) for Exceptional Conditions (§ 423.38)

This ICR is described in section 12.3.4. This represents a new burden requirement.

Table 18. Burden Summary for Enrollment Periods

Regulatory Citation	Subject	Response Type	Number of Respondents	Total Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.38(c)	SEP Enrollment	R	50	1,867,519	0.083	155,627	81.06	12,615,091

15.3.2 Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)

This ICR is described in section 12.3.10. This represents a new burden requirement.

Table 19. Burden Summary for Beneficiaries' Education on Opioid Risks and Alternative Treatments

Regulatory Reference	Provision Brief Title	Response Type**	Respondents	Total Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Programming Updates)	RK	308	103***	2	205***	91.96	18,882***
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Developing Materials)	RK	308	103***	2	205***	120.64	24,771***
§ 423.128(b)(11)	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Sending Materials Out by Mail)	TPD	308	36,446,413*	N/A	N/A	N/A	399,088*
	Subtotal	*Varies*	*308*	*36,446,618*	*Varies*	*410*	*Varies*	*442,741*

*Non-labor requirements and costs
**R (reporting), R (recordkeeping), and TPD (third party disclosure).
***Annualized burden

15.3.3 Safe Disposal of Controlled Substances for MTM Program Enrollees (§ 423.153(d)(1)(vii)(E))

This ICR is described in section 12.3.11. This represents a new burden requirement.

Table 20. Burden Summary for Safe Disposal of Controlled Substances for MTM Program

Regulatory Citation	Subject	Response Type**	Number of Respondents	Number of Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153(d)(1)(vii)(E)	Developing safe disposal materials	RK	942	314***	2	628***	120.64	75,762***
§ 423.153(d)(1)(vii)(E)	Programming updates for safe disposal materials	RK	942	314***	2	628***	91.96	57,751***
§ 423.153(d)(1)(vii)(E)	Mailing of safe disposal information (via TMR or other correspondence, not via CMR Standardized Format)*	TPD	942	937,495	n/a	n/a	n/a	10,266
	Subtotal	*Varies*	*942*	*938,123*	*Varies*	*1,256*	*Varies*	*143,779*

*Non-labor requirements and costs
**R (reporting), R (recordkeeping), and TPD (third party disclosure).
***Annualized burden

15.3.4 Mandatory Drug Management Programs (DMPs) (§ 423.153)

This ICR is described in section 12.3.11. This represents new burden requirement.

Table 21. Burden Summary for Mandatory DMPs

Regulatory Citation	Subject	Response Type*	Number of Respondents	Number of Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.153	Create DMP (rule, 4190-F2)	RK	78	26**	320	8,320**	120.77	1,004,806**
§ 423.153	Upload Notices (rule, 4190-F2)	RK	78	26**	5	130**	91.96	11,955**
§ 423.153	Conduct Case Management (rule, 4190-F2)	RK	78	157	5	785	112.2	88,077
§ 423.153	Send Notices (rule, 4190-F2)	TPD	8	8	0.1667	1.3336	54.64	73
§ 423.153	Report to CMS (rule, 4190-F2)	R	78	157	0.0167	2.6219	54.64	143
	Subtotal	*N/A*	*78*	*374*	*varies*	*9,239*	*varies*	*1,105,054*

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

15.3.5 Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153)

This ICR is described in section 12.3.11. This represents new burden requirement.

Table 22. Burden Summary for Beneficiaries with History of Opioid-Related Overdose Included in DMPs

Regulatory Citation	Provision Brief Title	Response Type *	# of Respondents	# of Annual Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost ($/hr)	Total Annual Cost ($)
§423.153	Revise Notices (rule, 4190-F2)	RK	309	103**	1	103**	54.64	5,628**
§ 423.153	Conduct Case Management (rule, 4190-F2)	RK	309	14,407	5	72,035	112.2	8,082,327
§ 423.153	Send Notices (rule, 4190-F2)	TPD	309	6,843	0.1667	1,141	54.64	62,329
§ 423.153	Report to CMS (rule, 4190-F2)	R	309	14,407	0.0167	241	54.64	13,146
	Subtotal	*N/A*	*309*	*35,760*	*varies*	*73,520*	*varies*	*8,163,430*

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

15.4 Summary of Rule and Non-Rule Burden Changes

Table 23. Summary of Rule and Non-Rule Burden Changes

Subject (Regulatory Citation)	Number of Respondents	Number of Responses	Total Annual Time (hr)	Total Annual Cost ($)
Added Burden				
ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§423.38), from Table 18	50	1,867,519	155,627	12,615,091
ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128). from Table 19	308	36,446,618	410	442,741
ICRs Regarding Safe Disposal of Controlled Substances for MTM Enrollees (§ 423.153(d)(1)(vii)(E)), from Table 20	942	938,123	1,256	143,779
Non-Rule Changes Associated with DMPs (§ 423.153), from Table 17	231	43,693	151,602	14,937,991
ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153), from Table 21	78	374	9,239	1,105,054

ICRs Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.153), from Table 22	309	35,760	73,520	8,163,430
SUBTOTAL: ADDITIONS	**942**	**39,332,087**	**391,654**	**37,408,086**
Removed Burden				
Enrollment Processes (Beneficiaries) (§ 423.32(a)), from Section 15.1.2	3,954,000	3,954,000	1,975,000	53,463,250
Enrollment Processes (Beneficiaries) (§ 423.32(b)), from Section 15.1.2	2,600,000	2,600,000	44,200	1,196,494
Business Continuity Plans (§§ 422.504(o) and 423.505(p)), from Table 16	85	85	13,560	1,099,173
Part D Sponsor's System Programming (§ 423.120(c)(6))*, from Section 15.1.4	30	30	93,600	10,264,768
Creation of Precluded Provider Model Notices to Medicare Beneficiaries and Prescribers (§ 423.120(c)(6))*, from Section 15.1.5	212	212	636	51,554
Preparation and Issuance of the Precluded Provider Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6))*, from Section 15.1.6	800	80,000	6,640	287,778
Furnishing EOB to Enrollees (§ 423.128(e)(5)), from Section 15.1.7	295	295	15,733	1,728,742
SUBTOTAL: REMOVALS	-6,555,422	-6,634,622	-2,149,369	-68,111,759
NET CHANGES of Added and Removed ICRs	**-6,554,480**	**32,697,465**	**-1,757,715**	**-30,683,673**

**One-time estimates that were not annualized in the last-approved version of this package, therefore not annualizing for this summary*

The previously approved supporting statement contained 625,627,848 responses and 8,683,706 burden hours. We are revising this estimate to **666,813,366 responses** and **6,973,844 burden hours** (see Table 15). **Total responses increased by 41,185,518** annually, however the **annual burden hours decreased by 1,709,862 hours**. The net change in burden reflects the addition and removal of ICRs as summarized in this section (see Table 23) as well as the changes in burden associated with existing ICRs updated to reflect the current numbers of Part D contracts. There was a net increase of 32,697,465 responses as a result of the addition and removal of ICRs from this package. The additional 8,488,053 responses (41,185,518 minus 32,697,465) is due to the increased number of Part D contracts in 2021 compared with the number of contracts in the previously approved supporting statement (942 vs 757, respectively). Similarly, because of the increased number of contracts, there was an additional 47,853 hours (1,757,715 minus 1,709,862) of burden which offsets the net of additional and removed ICRs in table 23.

CMS received no comments on these burden estimates during the 60-day comment period. None of the changes to information collection instruments described in section 12 affect burden calculations.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

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.