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

BACKGROUND

The Centers for Medicare and Medicaid Services (CMS) published a final rule (CMS-4068-F; RIN 0938-AN08) to establish the Medicare Prescription Drug Benefit on January 28, 2005 (70 FR 4194). The PRA requirements referenced in this PRA submission, as reflected in the final regulation, assisted in the implementation of the provisions of the Social Security Act (the Act) to establish and regulate the Medicare Prescription Drug Benefit and support the administration of the program.

The May 23, 2019 (84 FR 7912) final rule (CMS-4180-F, RIN 0938–AT92) required the inclusion of negotiated drug pricing information and lower cost alternatives in the Part D Explanation of Benefits beginning on 01/01/2021. The intent of the provision is to provide enrollees with greater transparency, thereby encouraging lower costs. The final rule also added certain new requirements for when MA plans may apply step therapy as a utilization management tool for Part B drugs. The rule also revised § 423.120(d) for Part B Step Therapy and § 423.128(e)(5) for Part D Explanation of Benefits. Section 423.120(d) provided protections to help ensure that beneficiaries maintain access to medically necessary Part B drugs while permitting MA plans to implement step therapy protocols. The rule required 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. Additionally, Part D sponsors were required to collect information on beneficiaries' prescription fills, in order to provide them with therapeutic alternatives for lower-cost drugs, based on their current prescription information.

This 2020 iteration proposes non-rule changes along with changes associated with a proposed rule (CMS-4190-P; RIN 0938-AT97) that published in the Federal Register on February 18, 2020 (85 FR 9002).

Summary of Non-rule Changes (Requirements/Burden)

In 2013, CMS issued detailed guidance to Part D sponsors which included expectations that CMS had for sponsors to address the urgent opioid crisis.[1] 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 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

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

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 CFR § 423.153(f). Burden associated with mandatory DMPs, as required by the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act), as proposed in CMS-4190-P, (RIN 0938-AT97), has been estimated for Part D sponsor parent organizations who have not already adopted DMPs. The purpose of this revision to PRA package 10141 is to quantify burden that had previously not been separately accounted for related to the adoption of DMPs by Part D sponsors.

Summary of Rule (CMS-4190-P) Changes (Requirements/Burden)

Educating MA and Part D Beneficiaries on Opioid Risks and Alternative Treatments On October 24, 2018 President Trump signed into law the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act; P.L. 115-271). The SUPPORT Act builds on several prior law aimed at addressing the opioid epidemic, including the Comprehensive Addiction and Recovery Act of 2016 (CARA; P.L. 114-98). CARA targeted the opioid crisis through public health and law enforcement strategies, and provided new authority for Part D sponsors to implement drug management programs for beneficiaries deemed at risk of misusing or abusing frequently abused drugs, such as opioids. These measures included limiting the number of prescribers and pharmacies used by such enrollees.

Mandatory Drug Management Programs The SUPPORT Act made changes to the requirements for Part D drug management programs (DMPs) to enhance Part D sponsors' ability to reduce the abuse or misuse of opioid medications in their prescription drug benefit plans. CMS is proposing two corresponding changes to the Part D drug management program provisions codified in § 423.153(f): 1) requiring Part D sponsors to adopt DMPs with respect to plans years on or after January 1, 2022, as required under Section 2004 of the SUPPORT Act; and 2) requiring inclusion of Part D beneficiaries with a history of opioid-related overdose in sponsors' DMPs beginning January 1, 2021, as required under Section 2006 of the SUPPORT Act. In addition, CMS is proposing to exempt beneficiaries with sickle cell disease from DMPs and proposing several technical clarifications to the DMP regulations, which are described in subsequent paragraphs.

Special Election Periods (SEPs) for Exceptional Conditions 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.

We are proposing to codify a number of SEPs that we have adopted and implemented through subregulatory guidance as exceptional circumstances SEPs. Codifying our current policy for these SEPs will provide 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 proposed

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.

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.

Section 6102 of the SUPPORT Act amends SSA section 1860D-4(a)(1) to require that, beginning in plan year 2021, Part D plans must provide enrollees with information regarding the treatment of pain, including the risks of prolonged opioid use and coverage of non-pharmacological therapies, devices, and non-opioid medications. Rather than disclosing the information to all enrollees, a plan sponsor may provide the information through mail or electronic communications to a subset of plan enrollees, such as enrollees who have been prescribed an opioid in the previous two-year service. We codified these requirements in 42 USC 1395w-104: *Beneficiary protections for qualified prescription drug coverage*.

CMS proposes to revise paragraph (a) of section 423.128, *Dissemination of Part D Plan Information*, to require that Medicare Advantage Prescription Drug Plans and standalone Part D Sponsors to include information on risks associated with opioids and coverage of nonpharmacological therapies and nonopioid medications. By “include information on risks associated with opioids and nonpharmacological therapies”, we propose that sponsors disseminate this information to any beneficiary who has received an opioid prescription in the past 14 days within a plan benefit’s calendar year. Medicare Advantage and Part D Prescription Drug plans are provided a model template to be used as a guide they will develop language with to send to beneficiaries. We believe providing plans with flexibility in creating language within the models is the most effective way for them to communicate the risks of opioid use in their beneficiary population.

As part of codifying the framework for DMPs in 2018, CMS codified a definition of an ARB in § 423.100. An ARB is defined as a Part D eligible individual--(1) who is—(i) Identified using clinical guidelines (as defined in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such FADs under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) With respect to

whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment. Please refer to sections III.A. and III.B. of this section of this proposed rule for more information about DMPs.

Under our proposed revisions to § 423.153(d) to implement sections 6064 and 6103 of the SUPPORT Act, at-risk beneficiaries, as defined in § 423.100 would be targeted for enrollment in a sponsor's MTM program. The existing criteria that Part D sponsors currently use to target beneficiaries for MTM program enrollment would remain unchanged, so that two groups of enrollees would now be targeted for enrollment: the first group would include enrollees who meet the existing criteria (multiple chronic diseases, multiple Part D drugs and drug costs); and the second group would include enrollees who are determined to be at-risk beneficiaries under § 423.100. The MTM program requirements would be the same for all targeted beneficiaries enrolled in a Part D sponsor's MTM program, regardless of whether they were targeted for enrollment based upon the existing criteria or because they are at-risk beneficiaries.

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)).

- 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), our 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.individual (§ 423.38(c)(8)).

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:

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. In the 2018 rule, 4182-F, CMS codified the definition of an ARB in § 423.100. An ARB is defined as a Part D eligible individual (1) who is (i) Identified using clinical guidelines (as defined in § 423.100); (ii) Not an exempted beneficiary; and (iii) Determined to be at-risk for misuse or abuse of such FADs under a Part D sponsor's drug management program in accordance with the requirements of § 423.153(f); or (2) with respect to whom a Part D sponsor receives a notice upon the beneficiary's enrollment in such sponsor's plan that the beneficiary was identified as an at-risk beneficiary (as defined in the paragraph (1) of this definition) under the prescription drug plan in which the beneficiary was most recently enrolled and such identification had not been terminated upon disenrollment.

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 6 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)

Upon receipt of a potential beneficiary's enrollment form, the Part D plan sponsor must provide the individual with prompt notice of acceptance or denial of the individual's enrollment request, in a format and manner specified by CMS.

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.

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.

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 Creation of Model Notices to the Medicare Beneficiaries and Prescribers

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 § 423.100 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 the Preparation and Issuance of the 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.
§ 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.

Enrollment requirements outlined in § 423.32 indicate that all PDP sponsors must have, at minimum, a paper enrollment form available for potential enrollees to request enrollment in a PDP. PDP sponsors may also accept enrollment elections made via the on-line enrollment center hosted by CMS, as well as requests for enrollment as described. These requirements apply to any beneficiary wishing to enroll in LIS as well.

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) in 4180-F 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, for example, to drug utilization management or dissemination of plan information, is an annually requirement; however, although bid information from sponsors is an annual collection, cost information is

collected monthly. Information collected from the states pertaining to low-income subsidy determinations and redeterminations is collected monthly.

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

7. Special Circumstances

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

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

8. Federal Register Notice/Outside Consultation

The proposed rule (CMS-4190-P; RIN 0938-AT97) will be published in the Federal Register on February 18, 2020 (85 FR 9002). We solicit public feedback to assist with the development and implementation of the provisions associated with this rule.

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 & Wages)

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) (No Changes)
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
(No Changes)
12.6 ICRs Regarding the Creation of Model Notices to the Medicare Beneficiaries and Prescribers
(No Changes)
12.7 ICRs Regarding the Preparation and Issuance of the Model Notices to the Medicare Beneficiaries and Prescribers
(No Changes)

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

- *WAGE ESTIMATES*

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Employment and Wage Estimates

BLS Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	35.52	35.52	71.04
Computer Programmer	15-1131	43.07	43.07	86.14
General Operations Manager	11-1021	59.56	59.56	119.12
Insurance Claim and Policy Processing Clerk	43-9041	20.26	20.26	40.52
Pharmacist	29-1051	59.45	59.45	118.90
Physicians and Surgeons	29-1060	101.43	101.43	202.86
Software Developers and Programmers	15-1130	50.23	50.23	100.46
Technicians, all other	19-4099	25.45	25.45	50.90

- *REQUIREMENTS AND ANNUAL BURDEN ESTIMATES*

The following information collection requests consist of six Information Collection Requests (ICRs) that remain unchanged (see sections 12.1, 12.2, 12.4, 12.5, 12.6, and 12.7. Revisions to section 12.3 are limited to subsection to 12.3.8 for Part B Step Therapy and subsection 12.3.9 for Part D Explanation of Benefits. As explained within this document, the changes are associated with the CMS-4190-P final rule.

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

12.1.1 Contract provisions (§§ 422.504 and 423.505)

Sections 422.504(o) and 423.505(p) require, respectively, MA organizations and Part D sponsors

to develop, maintain, and implement business continuity plans that identify potential business disruptions and develop ways to maintain functions or restore them as soon possible thereafter. We believe many entities already have developed and are maintaining plans that meet these requirements for two reasons - 1) creating business continuity plans is a well-established practice across most industries; and 2) CMS finalized a regulation (80 FR 7912) that created flexibility for industry practices related to business continuity. Accordingly, the burden associated with the requirement is the time and effort necessary for Part D sponsors and MA organizations without plans to develop and maintain business continuity plans and the time and effort for entities that have existing business continuity plans that do not meet all the requirements to revise them. For the first year, we estimate 28 entities do not have the plans in place and it will take 240 hours each to fulfill the business continuity requirements, for a total burden of **6,720 hours** (28 plans x 240 hr). We also estimate that there are 57 entities with existing plans that need to be updated and it will take **120 hours** to revise their business continuity plans in the first year, for a total burden of **6,840 hours** (6,720 hr + 120 hr) at a cost of $ 485,913.600 (6,840 hr x $71.04 for a business operations specialist.

In subsequent years, we estimate there will be 9 new Part D sponsors and MA organizations that do not already have a business continuity plan based on our experience that most entities that create new plans each year are under parent organizations that already have business continuity plans in place. We estimate a burden of 240 hours for each of these 9 entities. We also estimate that 5 entities with existing plans will either experience a problem or for some other reason update their plan and it will take each plan 40 hours for these revisions. For each subsequent year, we estimate 9 entities will not have the plans in place and it will take 240 hours each to fulfill the business continuity requirements, for a total burden of **2,160 hours** (240 hr x 9 plans). We also estimate for each subsequent year 5 entities with existing plans will need to update their business continuity plans and it will take 40 hours for each plan to make these revisions, for a total burden of **200 hours** (40 hr x 5 plans) at a cost of $ 14,208 200 hr x $71.04/ hr) r a business operations specialist.

Business Continuity Plans: Burden Summary **(**: Subtotal)

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

*RK (recordkeeping).

12.2 ICRs Regarding Medicare Prescription Drug Benefit Program (Benes) (§§ 423.32, 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)

(a) A Part D eligible who wishes to enroll in a Part D plan may enroll during the enrollment periods specified in § 423.38, by submitting an enrollment request to the Part D plan through one of the mechanisms CMS determines are appropriate.

The burden associated with this requirement is the time and effort necessary for an individual to submit the enrollment request to a Part D plan sponsor. We estimate that it will take 30 minutes (0.5 hours) to complete and submit the request to the Part D plan. Since the inception of the Part D program in 2006, more than 30 million individuals are enrolled in the program. Once enrolled, individuals are not required to complete an enrollment request to remain enrolled in their chosen plan year-to-year. Generally individuals are limited to changing Part D plans during the annual coordinated election period, and enrollment data indicates that individuals typically stay with a plan once enrolled. In the Fall of 2019, about 1.9 million individuals newly enrolled in or switched stand-alone Medicare prescription drug plans (PDPs) during the annual coordinated election period; these enrollments took effect on January 1 of 2018. New PDP enrollments (not counting those with a January 1 effective date) average approximately 186.000 per month. Therefore, it is estimated that a total of 3.954 million individuals may newly enroll in or change their PDP annually. The total burden is calculated to be **1,975,000 hours** (3,954,000 million enrollments x 0.5 hours).

(b) Enrollment form or CMS-approved mechanism. The enrollment request must be completed by the individual and include an acknowledgement by the beneficiary for disclosure and exchange of necessary information between the U.S. Department of Health and Human Services (or its designees) and the Part D plans sponsor. Persons who assist beneficiaries in completing the enrollment, including authorized representatives, must indicate they have provided assistance and their relationship to the beneficiary. The burden associated with this requirement is reflected above under section 423.32(a).

A Part D plan sponsor must require Part D eligible individuals enrolling or enrolled in its Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement, in a form and manner approved by CMS. All new enrollments require this information as part of the enrollment application (burden reflected under section 423.32(a)); however, plan sponsors may request currently enrolled members to provide this information upon indication of other insurance.

The burden associated with the requirement for individuals enrolled or enrolling in a Part D plan to provide information regarding reimbursement for Part D costs through other insurance, group health plan or other third-party payment arrangement is a total annual burden of 44,200 hours. We estimate that 2.6 million beneficiaries will need 1 minute (0.017 hours) to disclose reimbursement for Part D costs to the appropriate entity on an annual basis, for a total annual burden of **44,200 hours** (2,600,000 million beneficiaries x .017 hr).

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

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

The burden associated with this requirement is the time and effort put forth by the individual to actively decline enrollment or to actively enroll in a new, and for plans to process the enrollments and disenrollments. We estimate it will take an individual about 15 minutes (0.25 hours) to, either contact the plan to disenroll or contact the new plan to enroll (resulting in an automatic disenrollment from the plan into which the person was enrolled by CMS). Beneficiaries can contact plans in a number of ways, with varying amounts of time needed for the contact. A beneficiary will need to contact the plan only once. There are, on average, approximately 130,000 individuals who choose their own plan instead of the automatic enrollment each year so we estimate that it takes full dual beneficiaries 32,500 hours each year to decline the automatic enrollment or enroll in a different plan (causing a disenrollment). We further estimate the same amount of time for plans to receive and process these enrollments/disenrollments. The total number of hours is **32,500 hours** for the full dual beneficiaries (130,000 beneficiaries x .25 hr).

12.2.3 Enrollment periods (§ 423.38)

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

The burden associated with this requirement is the time and effort necessary for an individual to submit the required materials to CMS demonstrating that a Part D plan substantially violated a material provision of its contract. Based on our experience with the current Medicare Advantage program, we expect that fewer than 10 individuals, if any, will avail themselves of this option. Generally, in those instances where CMS has found that an MA organization has substantially violated a material provision of its contract, CMS has taken the necessary action on behalf of these individuals. Thus, we do not estimate any burden on individuals under this provision.

(c) We are proposing to codify certain Part C (at § 422.62(b)(4) through (b)(25)) and Part D (at § 423.38(c)(11) through (c)(32)) 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 proposing to establish two 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 do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact on the Medicare Trust Fund.

Our proposal represents the codification of existing policy on SEPs for exceptional circumstances that has been specified in sub-regulatory guidance for quite some time, as well as the addition of the two aforementioned new SEPs for exceptional circumstances. MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for determining an applicant's eligibility for an election period has not previously been submitted to OMB, we are seeking their approval under the aforementioned OMB control numbers.
We estimate it would take approximately 5 minutes (5/60 hr) at $74.00/hr for a business operations specialist to determine an applicant's eligibility for an election period.

The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 5 min/60) at a cost of $11,051,267 (155,564 hours * $74.00/hr) or $217,290 per Part D parent organization ($11,516,367/53 Part D parent organization).

Regulatory Citation	Response Type	Subject	Respondents	Number of Respondents	Time per Response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
§ 423.38	R	Enrollment	SEP D	1,867,519	5/60	15 5,564	74.00	11,0 51,267	11,051,267

*R (reporting).

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

If an individual establishes to CMS that he or she was not adequately informed that he or she no longer had creditable prescription drug coverage or the coverage is involuntarily reduced, the individual may apply to CMS to have the coverage treated as creditable coverage so as to not be subject to the late enrollment penalty described in § 423.46. The burden associated with this requirement is the time and effort necessary for an individual to apply to CMS to have such coverage treated as creditable coverage. Based on recent experience (i.e., 2012 – 2014, we estimate that on an annual basis it will take 100 individuals 15 minutes (0.25 hours) to apply to CMS, for a total of **25 hours** (100 beneficiaries x .25 hr).

12.2.5 Exceptions process (§ 423.578)

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

The burden associated with this requirement is the time and effort necessary for an individual to submit an exception request. We estimate that that 3,185,000 exception requests will be received by 424 Part D plan sponsors. We further estimate it will take an individual an average of 15 minutes (0.25 hours) to provide the request for a total annual burden of **796,250 hours** (3,185,000 requests x .25 hr).

12.2.6 Burden Summary

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

CFR Section	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.32(a) and (b)	R	3,954,000	0.5	1	3,954,000	1,975,000
423.32(b)	TPD	2,600,000	0.017 (1 min)	1	2,600,000	44,200
423.34(e)	R	130,000	0.25	1	130,000	32,500
423.56(f)	RK	100	0.25	1	100	25
423.578(a) and (b)	R	3,185,000	0.25	1	3,185,000	796,250
Subtotal (Reporting)		*7,269,000*	*Varies*	*1*	*7,269,000*	*2,803,750*
423.56(f)	RK	100	0.25	1	100	25
Subtotal		**9,869,100**	**Varies**	**1**	**9,869,100**	**2,847,975**

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

12.3 ICRs Regarding Medicare Prescription Drug Benefit Program (Plans) (§§ 423.32, 423.34, 423.36, 423.44, 423.46, , 423.104, 423.120, 423.128, 423.153, 423.168, 423.171, 423.907, 423.329, 423.336, 423.343, 423.464, 423.505, 423.552, 423.56, 423.564,423.568, 423.570, 423.572, 423.578, 423.800, and 423.892).

(Revisions to section 12.3 are limited to 12.3.7 (§ 423.100) Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100) in and Part D Dissemination of Information under section 12.3.9 (§ 423.128))

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)

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

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide an individual notice of acceptance or denial of the individual's enrollment request. Every enrollment request requires a response from the Part D plan so that the individual knows if he or she will be covered under the plan. There are approximately 912 Part D plan sponsors in 2019 . Each Part D plan creates the acceptance and denial notices, and most plans

continue to use the same notice year-after-year, with some minor adjustments. Therefore, we estimate that it will take each Part D plan approximately 3 hours to produce each notice –an acceptance and a denial notice. 912 plan sponsors x (3 hours x 2 notices) = **5,472** . We further estimate that on average, it will take each Part D plan sponsor 1 minute (0.017 hours) for a business operations specialist to assemble and disseminate the proper notice for each of the enrollment requests received annually. 3.954 million requests x 0.017 hours (1 minute each) = **67,218 hours**. The total number of hours is **72,690** (5,472+ 67,218) or 79.70 hours per sponsor annually. The estimated annual cost is $5,163,898 ($71.04 / hr x 72,690 hr).

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

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

The burden associated with this requirement is the time and effort put forth by the individual to actively decline automatic enrollment or to actively enroll in a new, and for plans to process the enrollments and disenrollments. We estimate it will take an individual about 15 minutes (0.25 hours) to, either contact the plan to decline the automatic enrollment or contact a different plan to enroll (resulting in an automatic disenrollment from the plan into which the person was enrolled by CMS). Beneficiaries can contact plans in a number of ways, with varying amounts of time needed for the contact. A beneficiary will need to contact the plan only once. There are on average approximately 130,000 individuals who choose their own plan instead of the automatic enrollment each year so we estimate that it takes full dual beneficiaries 32,500 hours a year to decline the automatic enrollment or enroll in a different plan (causing a disenrollment) each year. We further estimate the same amount of time for plans to receive and process these declinations/enrollments. The total burden is **32,500 hours** for a business operations specialist for the 912Part D plan sponsors. The estimated annual cost is $2,308,800 ($71.04 /hr x 32,500 hr).

12.3.3 Disenrollment process (§ 423.36)

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

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to provide an individual a notice of disenrollment, whether it is the result of the individual leaving the Part D program or switching plans during a valid enrollment period. Based on disenrollment data for January through August 2019, we estimate that on an annual basis it will require a total of 1,903,752 notices, affecting each Part D plan sponsors to some degree, as described below. There are approximately 912 Part D plan sponsors in 2019. 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.

912 plan sponsors x 1 hour = **912** 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 **33,276 hours** (912 + 32,364) or 42.8 hours per sponsor annually. The estimated annual cost is $2,363,927 ($71.04 /hr x 33,276 hr).

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

If the disenrollment is for any of the reasons specified in paragraphs (b)(1), (b)(2)(i) or (b)(2)(iv) of § 423.44, the Part D plan sponsor must give the individual timely notice of the disenrollment with an explanation of why the Part D plan is seeking to disenroll the individual. Notices for these reasons must be provided to the individual before submission of the disenrollment notice to CMS; and include an explanation of the individual's right to a hearing under the Part D plan's grievance procedures.

A Part D plan sponsor may disenroll an individual from the Part D plan for failure to pay plan premiums following a minimum 2-month grace period and if the Part D plan sponsor can demonstrate to CMS that it made reasonable efforts to collect the unpaid premium amount.

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to effectuate the disenrollment and provide an individual the notice of disenrollment. There were approximately 912 Part D plan sponsors in 2019. 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. 912 plan sponsors x 1 hour = **912 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 2019, we estimate that on an annual basis 496,344 individuals will be disenrolled for failure to pay premiums. 496,344 notices x 0.1 hours (6 minutes each) = **49,634 hours**. The total number of hours is **50,546** (912 + 49,634) or 55.4 hours per sponsor annually. The estimated annual cost is $3, 590,788 ($71.04 /hr x 50,546 hr).

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

The burden associated with this requirement is the time and effort for the Part D plan sponsor to disclose to an individual the notice of disenrollment. There are approximately 912 Part D plan sponsors in 2019 . 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. 912plan sponsors x

1 hour = **912 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, 2019, 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 **930.7** (912 + 18.7) or 1.02 hours per sponsor annually. The estimated annual cost is $66,117 ($71.04 /hr x 930.7 hr).

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

The Part D plan sponsor burden associated with this requirement is the time and effort for the Part D plan sponsor to provide an individual the notice of the owed plan premium amount required for reinstatement. There are approximately 912 Part D plan sponsors in 2019 . 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. 912plan sponsors x 1 hour = **912 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 **2,689** (912+ 1,777) or 3.24 hours per sponsor annually. The estimated annual cost is $ 191,027 ($71.04 /hr x 2,689 hr).

A Part D plan may disenroll an individual whose behavior is disruptive, only after it meets the requirements described in guidance and after CMS has reviewed and approved the request. To disenroll an individual from its Part D plan, based on an individual's behavior, the Part D plan sponsor must document the enrollee's behavior, its own efforts to resolve any problems and any extenuating circumstances. The Part D plan must submit this information and any documentation received by the beneficiary to CMS. The Part D plan sponsor may request from CMS the ability to decline future enrollment by the individual.

The burden associated with this requirement is the time and effort necessary for a Part D plan to document and retain the documentation that meets the requirements set forth in guidance. We estimate that it will take a Part D plan 3 hours to capture and retain the required documentation for each occurrence. Based on actual experience, CMS receives approximately 1-2 total requests for involuntary disenrollment due to disruptive behavior annually. Thus, the burden to Part D plan sponsors is negligible.

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

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

When a Part D plan contract terminates as stipulated under §§ 423.507 and 423.510 the Part D plan sponsor must send a notice to the enrollee before the effective date of the plan termination. The notice must give provide an effective date of the plan termination and a description of alternatives for obtaining benefits under Part D. The burden associated with these requirements is discussed below under §§ §§ 423.507 and 423.510.

12.3.5 Late enrollment penalty (§ 423.46)

Section 423.46(b) states that Part D sponsors must obtain information on prior creditable coverage from all enrolled or enrolling beneficiaries and report this information to CMS in a form and manner determined by CMS. Individuals enrolling in Part D with 63 days or more without creditable coverage will be assessed a Part D late enrollment penalty.

The burden associated with this requirement is the time and effort put forth by the Part D sponsor to obtain the required information. There are approximately 912 Part D plan sponsors in 2019. 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 $70,223,040 ($71.04 /hr x 988,500 hr)..

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

The burden associated with this requirement is the time and effort put forth by the Part D plan sponsor to retain the required information. To comply with this requirement, Part D sponsors will expend 5 minutes (0.083 hours) per new Part D enrollee. We estimate that a total of 3.954 million individuals may newly enroll in or change their Part D plan annually. We estimate the total annual burden associated with this requirement will be **328,182 hours** for all new Part D enrollees. The estimated annual cost is $23,314,049 ($71.04 /hr x 328,182 hr).

12.3.6 Information about Part D (§ 423.48)

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

The burden associated with this requirement is the time and effort necessary for a Part D sponsor to submit the required materials to CMS. We estimate that on an annual basis it will take 912

912 Part D sponsors 2 hours for a business operations specialist to submit the required documentation to CMS for a total annual burden of **1,514 hours**. The decrease in total annual burden from the previous estimate is due to the decreased number of respondents. The estimated annual cost is $106,403 ($71.04 /hr x 1,514 hr).

12.3.7 Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

4190-P would require Part D sponsors under § 423.100 to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors would mean that additional beneficiaries would be reported by OMS as PARBs.

The estimated reporting burden associated with these new PARBs has three of the four aspects of the burden we estimated for mandatory DMPs, as previously described. Under § 423.153(f), sponsors must: (1) conduct case management, which includes sending written information about PARBs to prescribers; (2) issue written notices to PARBs and ARBs; and (3) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx. The assumptions surrounding case management by plan sponsors in the previous section were applied to the estimated population of 18,268 PARBs projected to be identified annually under this proposal. In aggregate, we estimate an annual burden for a projected 18,268 enrollees annually newly subject to case management, including sending the required written information to the prescribers of PARBs, under this proposal to cost $ 9,909,659.28 per year (18,268 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

In order to estimate the impact of providing beneficiary notices, we must consider two main populations: 1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS based on internal data estimates as 22,516 PARBs) and 2) beneficiaries with a history of opioid-related overdose (which as just indicated, CMS, based on internal data, estimates as 18,268 PARBs).

We believe the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event. We estimate that about 47.5 percent or (8,677 beneficiaries (18,268 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 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.

This is in contrast to the PARBs meeting OMS minimum and supplemental criteria, where Part D program experience demonstrates a significantly lower incidence of coverage limitations (that is, only about 1,1251,126 or 5 percent% of the 22,516 beneficiaries receive a first notice.) .

Following these assumptions, of the 40,784 (22,516 PARBs + 18,268 PARBs) Part D beneficiaries projected to be potentially at-risk, either by meeting the OMS criteria (22,516

PARBs) or the history of opioid-related overdose as defined (18,268 PARBs), those receiving a first notice from their plan sponsor informing them of the sponsor's intention to apply a coverage limitation are projected to total 9,803 enrollees (8,677 with history of opioid-related overdose + 1,126 meeting OMS minimum and supplemental criteria), or 24 percent of PARBs (40,784 (22,516 + 18,268) x 0.24).

We estimate it would take 10 minutes (0.1667 hr) at $50.90/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, we estimate an annual burden of 1,446 hours (8,677 enrollees * 0.1667 hr) at a cost of $73,601 (1,446 hrs * $50.90/hr).

Evaluation of the use of POS claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, we do not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, we recognize that this proposed change is projected to nearly approximately double the number of beneficiaries CMS identifies to sponsors as PARBs and accordingly solicit comment as to whether including beneficiaries with a history of opioid-related overdose and the projected doubling in identified PARBs is expected to significantly modify the approach or response to non-exempted beneficiaries and their case management require significant modifications by sponsors to respond to this increase in case management volume.

We estimate it would to take no more than 1 hours per sponsor. A at $50.90/hr for a health technician to draft and implement such changes. In aggregate we estimate program-wide reporting-related one-time burden of first year impact is 288 hours (288 sponsors x* 1 hr/reponse/hour to revise notices) at a cost of $14,659 (288 hr sponsors x [1hr/sponsor] x [$50.90/1hr]).

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, would need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Proposed changes to the model beneficiary notices will be submitted to OMB for approval under control number 0938-0964 (CMS-10141). Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal.

With respect to the burden of disclosure of DMP data to CMS associated with the increase in PARBs, we estimate that it will take sponsors on average 1 minute (0.017 hr1/60) per 18,268 beneficiaries to document OMS and or MARx the outcome of case management and any

applicable coverage limitations. Thus the aggregate we estimate an annual burden of 305 hours (18,268 PARBs x* 1 minute / 60 minutes/0.0171/60 hr) at an annual cost burden of $15,525,830 (305 hrs x * $50.90/hr per hour)) for a health technician to enter the disclosed information.

With respect to the burden of disclosure of DMP data to CMS associated with the increase in PARBs, we estimate that it will take sponsors on average 1 minute (1/60) per 18,268 beneficiaries to document OMS and or MARx the outcome of case management and any applicable coverage limitations. In aggregate we estimate an annual burden of 304.5 hours (18,268 PARBs x 1/60 hr) at a cost of $15,525 (304.5 hr x $50.90/hr) for a health technician to enter the disclosed information.

Table X on the following summarizes the six DMP provisions whose impact is discussed in ICR#3 and ICR #4 of this proposed rule.

Table J4: SUMMARY FOR MANDATORY DMPs AND IDENTIFICATION OF ADDITIONAL PARBs

Provision Brief Title	Response Type*	# of Respondents	Total Responses	Hours per Respondent	Total Hours	Labor Cost ($/hr)	Total Annual Cost ($)
§423.100	DMP Notice Revisions	RK	79	0.0167	8,677	1446	50.90	73,601
§ 423.100	DMP Notice Revisions	RK	288	1.00	288	288.0	50.90	14,659
§ 423.100	DMP Notice Revisions	RK	18,268	305	0.0167	15,258	50.90	15,528
§ 423.153	DMP Notice Revisions	RK	79	80.00	6,320.0	3,008,573	476.0	3,008,573
Subtotal		*N/A*	*18,714*	*9,350*	*varies*	*3,025,565*	*varies*	

*RK (recordkeeping).

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

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

The burden associated with this requirement is the time and effort necessary for a Part D plan sponsor to disclose to CMS the aggregate negotiated price data on concessions. Given the complexity of this reporting, we estimate the time and effort required will be similar to that associated with the payment-related reporting requirements. Therefore, we estimate that on an annual basis it will take each of the 912 respondents 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,120 hours**. The estimated annual cost is $537,773 ($71.04 /hr x 9,120 hr).

12.3.8 Access to covered Part D drugs (§ 423.120)
(No changes (d))

(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 912 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 **1,824 hours**. The decrease in total annual burden from the previous estimate is due to the decreased number of respondents. The estimated annual cost is $129,577 ($71.04 /hr x 1,824 hr).

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

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

Given that each entity has already created disclosure notices for mass mailings, we estimate that on an annual basis it will take on average, each of the 912 respondents 40 hours for a business operations specialist to disclose the required notice for a total annual burden of **36,480 hours**. The decrease in total annual burden from the estimate previously reported is due to the decreased number of respondents. The estimated annual cost is $2,591,539 ($71.04 /hr x 36,480 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 $112,030,080 ($71.04 /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 $71.04/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 634 hours (1 hr x [697 plans - 63 Prescription Drug plans which do not offer Part B]) at a cost of $45,039 (634 hr x $71.04/hr).

Regulatory Reference	Provision Brief Title	Respondents	Response Type*	Total Responses	Hours per Respondent	Total Hours	Labor Cost ($/hr)	T An Co
§ 423.128	Part D Explanation of Benefits (Updating Systems)	288	RK	288	160	15,733	98.54	1,5
§ 423.128	Part D Explanation of Benefits (Extra	288	TPD	571,200,000	n/a	n/a	n/a	5,7

	mailings)*							
§ §423.120, 422.136, 422.568, 422.570, 422.572, 422.584, 422.590, 422.618, and 422.619	Part B Step Therapy (use of PT Committee)	634	R	634	1	634	72.84	
TOTAL		**929**	**n/a**	**571,201,147**	**Varies**	**16,403**	**Varies**	**7,**

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

12.3.9 Dissemination of plan information (§ 423.128)
(Revised by adding requirements under subsection (a)

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 912 respondents 80 hours on an annual basis to prepare the plan materials. We further estimate that, on average, it will require each entity 120 hours for a business operations specialist to disseminate the required materials to enrollees and eligible individuals for a total annual burden of **182,400 hours**. The decrease in total annual burden from the previously reported estimate is due to a correction in the number of respondents. The estimated annual cost is $12,957,696 ($ 71.04 /hr x 182,400 hr).

423.128(a)(2) states that the information disclosed under § 423.128 must be done "in the manner specified by CMS in a clear, accurate, and standardized form." To assist Part D sponsors in developing clear, accurate, and standardized forms to provide to the enrollee subset, we plan to provide MA-PDs and standalone PDPs annually with information on the non-pharmacological therapies, devices, and non-opioid medications for the treatment of pain under the Medicare fee-for-service program. Part D sponsors would be able to be use this information in developing standardized forms to convey the required opioid risk and alternate pain treatment coverage information to the enrollee subset.

CMS does not have the authority to recommend a cohort of enrollees to whom to send these notifications. There are several Part D enrollee groups presented in section III.D. of this proposed rule that we suggest could be sent the required information and thus, several approaches to estimate the burden. These enrollee group estimates range from sending the information to 46,759,911 enrollees to 2,698,064 enrollees.

Before Part D and MA-PD parent organizations can send this information to these beneficiaries, they would have to create and upload materials into their internal systems based on summary information that CMS would provide. We estimate that 288 Part D and MA-PD parent organizations would be subject to this proposal, based on 2019 data. We estimate that it will take on average 2 hours at $86.14/hr for a computer programmer to upload the information into the

systems. This would result in a one-time burden of 576 hours (2 hr x 288 parent organizations) at a cost of $49,617 (576 hours x $86.14/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.

We also estimate a one-time burden of 2 hours at $118.90/hr for a pharmacist to develop the materials(s) to be sent to the beneficiaries. In aggregate we estimate a one time burden of 576 hours (288 parent organizations x 2 hr) at a cost of $ 68,486 (576 hr x $118.90/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).

We propose that 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 hard mail. 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.

In making estimates on the burden of sending out notices, we assume that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs per enrollee are paper, toner, and postage. We also assume one page per notice and 2,862,548 enrollees (3,816,731 enrollees x 0.75 who want a paper copy). We therefore estimate:

i) Total cost of paper: Typical wholesale costs of paper are approximately $2.50 for a ream of 500 sheets. Thus the paper cost is $14,313 (2,862,548 enrollees x 1 additional page per enrollee x $2.50/500 sheets).
ii) Total cost of toner: Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 sheets. CMS assumes a cost of $50.00 for 10,000 pages. Therefore the toner cost is $14,313 (2,862,548 enrollees x 1 added page per notice x $50/10,000 sheets).
iii) Total cost of postage: For 2019 the bulk postage rates are $0.19 per 200 pages Therefore, the cost of postage $2,719 (2,862,548 enrollees x 1 added page per notice x $0.19/200 pieces).
Thus the aggregate cost of mailing notices each year to all affected enrollees would be $31,345 ($14,313 cost of paper + $14,313 cost of toner + $2,719 cost of postage) Table X summarizes the costs. Note that mailing costs are annual while the programming updates and the development of materials are first year costs with minimal or no costs in future years

We have scored our suggested approach of 30 day continuous opioid usage with at most a 7 day gap. Our initial reasoning in selecting this approach as most reasonable, is because we assume that plans did not want to, for example, burden enrollees coming out of surgery and in need of pain relief.

However, the Support Act does not require CMS to set a standard. The Support Act gives plans maximum flexibility; they may choose to send the information to any subset of their choosing, including all enrollees.

For plans convenience and planning, Table J9, in Section X, presents a cost analysis of a wide range of alternatives including sending notices to all enrollees or to selected subsets. As can be seen, the range of costs are $0.1 to $0.5 million(for sending notices by paper to all Part D enrollees).

Rather than take an average of these alternatives without any experience or feedback, and especially considering that costs are not an issue, we solicit stakeholder feedback on which alternatives they think are most likely and unlikely as well as stakeholder feedback on our estimation of printing and delivery costs.

TABLE J6: Impacts of this Provision by SUBJECT

Subject	**Number of Respondents**	**Response Type**	**Time per Response (hr)**	**Total Time (hr)**	**Labor Cost ($/hr)**	**Total Cost in 1st Year ($)**	**Total Cost in Subsequent Years ($)**
Programming updates	288	RK	2	576	86.14	49,617	n/a
Developing materials	288	R	2	576	118.90	68,486	n/a
Sending out materials by mail (75% prefer receiving this)	2,862,548	TPD	NA	NA	NA	31,345	varies
	7,163,615	TPD	NA	NA	NA	176,934	varies
	11,027,271	TPD				208,665	varies
	16,134,063	TPD				250,604	varies
Total	Varies	N/A	Varies	792	Varies	Varies	Varies

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

Under paragraph (e), Part D sponsors must furnish directly to enrollees an explanation of benefits when prescription drug benefits are provided under qualified prescription drug coverage that meets the requirements set forth in this section. The burden associated with this requirement is the time and effort necessary for 912 respondents to provide an explanation of benefits when prescription drug benefits are provided to enrollees. We estimate that it will require each entity 160 hours for a business operations specialist to disseminate the required materials for total annual burden of **145,920 hours**. The decrease in total annual burden from the previously reported estimate is due to a correction in the number of respondents. The estimated annual cost is $10,366,157 ($71.04/hr x 145,920 hr).

In accordance with § 423.128(e)(5) of CMS-4180-F, sponsors will be 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 will also be required to include information about drugs that are therapeutic alternatives with lower cost-sharing. The intent is to provide enrollees with greater transparency with respect to drug prices, leading to lower costs. Since plans use formularies, they already have the negotiated drug price and the lower cost alternatives in an existing information system. The cost of this provision consists of: programming systems to calculate and connect information to the Part D EOB production, and the cost of paper, toner, and postage.

We estimate it will take two software programmers 8 hours (16 hours total) to revise 10 systems at $ 100.46/hr. We also believe it is appropriate to estimate burden by each parent organization since it is typically more efficient for major system changes to be performed once at the parent organizational level with the contracts of that parent organization sharing the updated system.

Based on bid information and trends we expect 288 Part D Sponsors and PDP parent organizations for 2020. In aggregate, our revised one-time burden estimate for updating systems is 46,080 hours (160 hr per response x 288 responses) at a cost of $4,629,197 (46,080 hr x $100.46/hr) or $16,074 per respondent ($4,629,197/288 sponsors and organizations). Over the course of OMB's anticipated 3-year approval period, we estimate an annual burden of 15,733 hours (46,080 hr/3 years) at a cost of $1,543,066 ($4,629,197/3 years). We are annualizing the one-time labor estimate since we do not anticipate any additional burden after the 3-year approval period expires.

We also estimate an ongoing burden since EOBs would contain additional information about alternatives possibly requiring more printed pages per EOB. Based on internal bid information and projection we expect 47.6 million Part D enrollees in 2020. 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 2019 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 2019 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 2019 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 $5,733,706 (47.6 million enrollees x 12 months x 1 page x $0.010038 per page). We believe that after appropriate programming (as discussed previously) the 47.6 million mailings will be performed automatically and will not require extra staff time.

Combining the estimates for system updates and mailing we obtain an annual estimated cost of $7,284,069 ($1,550,363 for updating systems + $5,733,706 for paper, printing, and mailing)

Regulatory Reference	Provision Brief Title	Respondents	Response Type**	Total Responses	Hours per Respondent	Total Hours	Labor Cost ($/hr)	Total Annual Cost ($)
§ 423.128	Part D Explanation of Benefits (Updating Systems)	288	RK	288	160	15,733	100.46	1,543,066
§ 423.128	Part D Explanation of Benefits (Extra mailings)*	288	TPD	571,200,000	160	145,920	71.04	5,733,706*
§ 423.128	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Programming Updates)	288	RK	288	2	576	86.14	49,617
§ 423.128	Educating MA and Part D	288	R	288	2	576	118.90	68,486

	beneficiaries on opioid risks and alternative treatments (Developing Materials)							
§ 423.128	Educating MA and Part D beneficiaries on opioid risks and alternative treatments (Sending Materials Out by Mail)	288	TPD	2,862,548	NA	NA	NA	31,345
TOTAL				**574,062,836**		*Varies*		**7,426,220**

*Non-labor requirements and costs

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

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

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 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. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on analysis of the first 3 quarters (January, April, and July 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate, we can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

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. 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 $118.90/hr, 2 hours would be conducted by a health technician ("Technician, All other") at $50.90/hr, and 1 hour would be conducted by a physician at $202.86/hr to work directly with providers on discussing

available options and determining the best course of action. In aggregate, we estimate an annual burden for an estimated 158 enrollees annually newly subject to case management under this proposal to cost $85,708.68 per year (158 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

The 79 Part D parent organizations affected by this proposal also would have to upload beneficiary notices into their internal claims systems before they could issue them. We estimate that it will take each, on average, 5 hours at $86.14/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 estimate a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $34,025 (395 hr * $86.14/hr).

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimate that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). Since fewer than 10 beneficiaries are affected by this, the burden of sending these notices is exempt from PRA.

As to disclosure of DMP case management outcomes data to CMS pursuant to § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy would 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 sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually * 0.0167 hr) at a cost of $134 (2.6386 hr * $50.90/hr).

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 912 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 **456 hours**. The decrease in total annual burden from the previously reported estimate is due to the decrease in the number of Part D plans. The estimated annual cost is $ 32,394 ($71.04 /hr x 456 hr).

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

The burden associated with this requirement is the time and effort necessary for the Part D plan sponsor or MA organization offering a MA-PD plan to provide CMS with information concerning its quality assurance measures and systems, according to guidelines specified by CMS. We estimate that it will require 912 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 **456 hours**. The decrease in total annual burden from the previously reported estimate

is due to the decrease in the mean wage for a business operations specialist. The estimated annual cost is $ 32,394 ($71.04 /hr x 456 hr).

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

Since 2013, there have been 4,617 POS edits submitted into MARx by plan sponsors for 3,961 unique beneficiaries as a result of the drug utilization review policy. That results in approximately 923 edits annually. If we assume that the number of edits or access to coverage limitations will double due to the addition of pharmacy and prescriber "lock-in" to OMS, to approximately 1,846 such limitations, we estimate 3,692 initial and, second notices (number of limitations (1,846) multiplied by the number of notices (2)) total corresponding to such edits/limitations. Once the templates have been developed, we estimate it will take an average of 5 minutes (0.083 hours) at $39.22/hour for an insurance claim and policy processing clerk to prepare each notice. We estimate an annual burden of **306 hours** (3,692 notices x 0.083 hour) at a cost of $12,399 (306 hr x $40.52 /hr).

Part D plan sponsors are required to upload these new notice templates into their internal claims systems. We estimate that 219 Part D plan sponsors (31 PDP parent organizations and 188 MA-PD parent organizations, based on plan year 2019 plan participation) will be subject to this requirement. We estimate that it will take on average 5 hours at $86.14/hour for a computer programmer to upload the notices into their claims systems. This will result in a total burden of **1,095 hours** (5 hour x 219 sponsors) at a cost of $94,323 (1,095 hr x $86.14 /hr).

In aggregate, the burden to upload and prepare these additional notices is **1,401 hours** (306 hours +1,095 hours) at a cost of $104,248 ($12,399 + $94,323).

Non-Rule Related ICRs Related to 12.3.10

Although voluntary under 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. 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. For the 2019 plan year, the 669 Part D contracts were represented by 209 parent organizations.

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 clinical and non-clinical staff to design its DMP. Thus, we estimate 16,720 hours (209 parent organizations * 80 hr) for parent organizations to develop DMPs consistent with the requirements of §423.153(f).

We estimate that development likely requires two pharmacists (working at $118.90/hr) and two general operation managers (working at $119.12/hr) per organization. Thus, the hourly wage for the organization's development team is $476.04 [2 pharmacists * $118.90/hr] + [2 managers * $119.12/hr]. The labor rates for the development team are summarized below.

LABOR RATES FOR THE DMP DEVELOPMENT TEAM

Occupation	Adjusted Hourly Wage ($/hr)	Number of Staff	Total Wages ($/hr)
General operations manager	119.12	2	238.24
Pharmacist	118.90	2	237.80
TOTAL	238.02	4	476.04

Each of the 209 parent organizations are expected to spend 80 hours at a cost of $38,083 (80 hr * $476.04/hr) for the team of four professionals to develop the DMP. The aggregate burden is therefore 16,270 hours (209 parent organizations * 80 hr) at a cost of $7,959,389 (16,270 hr * $476.04/hr).

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. This package includes the Sample Prescriber Inquiry Letter (see attachment 6e) which sponsors use in the case management process. 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 $118.90/hr, 2 hours would be conducted by a health technician ("Technician, All other") at $50.90/hr, and 1 hour would be conducted by a physician at $202.86/hr to work directly with providers on discussing available options and determining the best course of action. In aggregate, we estimate annual burden for an estimated 22,358 enrollees annually subject to case management to cost $12,128,321 per year (22,358 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

The parent organizations have to upload model notices and written communication materials associated with DMPs into their internal systems in order to issue them. The notices include initial notice, second notice, and alternate second notice (already submitted under the PRA package with revisions associated with proposed rule CMS 4190-P (RIN 0938-AT97), as applicable, and submitted to OMB for approval under control number 0938-0964); sample prescriber inquiry letter (see attachment 6e); and beneficiary transfer letter (see attachment 6f).

The cost burden associated with a computer programmer uploading all notices into sponsor claims systems was already added to this PRA package revision associated with final rule 4182-F. This burden is not being recalculated in this revision as it has already been accounted for.

As a result of case management, a proportion of PARBs 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. Approximately 5 percent of PARBs identified by minimum OMS criteria receive an initial and second notice (or alternate second notice). The cost burden associated with sending a second (or alternate second) notice was already addressed in the revision to this PRA package associated with final rule 4182-F and proposed rule CMS 4190-P (RIN 0938-AT97), as applicable, and submitted to OMB for approval under control number 0938-0964. The burden for the second notice (or alternate second notice) is not being recalculated in this revision as it has already been accounted for under Section 12.3.7, titled Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100). The burden associated with sending the initial notice was not calculated at that time. Therefore, in this revision, we calculate the burden associated with sending the initial notice to PARBs. CMS data estimates that annually 22,358 PARBs will be identified based on minimum OMS criteria. Therefore, it follows that approximately 1118 (22,358 * 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 $50.90/hr for a health technician to send the initial notice. In aggregate, we estimate an annual burden of 93.1667 hours (1118 enrollees * 0.0833 hr) at a cost of $4,742 (93.1667 hr * $50.90/hr) to be attributed to the initial notice requirements. As previously stated, the initial notice, second notice, and alternate second notice have already been submitted at attachments under the PRA package with revisions associated with proposed rule CMS 4190-P (RIN 0938-AT97), as applicable, and submitted to OMB for approval under control number 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 $50.90/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 373.3786 hours (22,358 PARBs * 0.0167 hr) at a cost of $19,005 (373.3786 hr * $50.90/hr).

Plan sponsors are required to transfer case management information upon the request of a new sponsor as soon as possible but not later than 2 weeks from the new sponsor's request when a PARB or ARB switches plans and any limitation implemented by the former sponsor has not expired before the beneficiary's disenrollment. CMS provides a sample transfer memo that

sponsors may use to transfer such information (see attachment 6f). According to internal CMS data from the first quarter of 2019, 11 such beneficiaries switched plans. We estimate it takes sponsors on average 1 hour at $50.90/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 $560 (11 beneficiaries * 1 hr * $50.90/hr) to complete information transfer requests.

This collection of information request is related to the drug management notices that will be added to the sponsors' claims system. The notices include initial notice, second notice, and alternate second notice; sample prescriber inquiry letter (see attachment 6e); and beneficiary transfer letter (see attachment 6f).

The cost associated with a computer programmer uploading all notices into sponsor claims systems was already added to this PRA package revision associated with final rule 4182-F. This burden is not being already been submitted at attachments in this revision as it has already been accounted for under section 12.3.7, titled Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)
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The cost associated with sending a second (or alternate second) notice was already addressed in the revision to this PRA package associated with final rule CMS-4182-F and proposed rule CMS 4190-P, as applicable. The burden for the second notice (or alternate second notice) is not being recalculated in this revision as it has already been accounted for under section 12.3.7, titled

Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100).

12.3.11 Accreditation Organizations and Treatment of Territories (§ 423.168, 423.171, and 423.907)

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 requirement 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 1.0 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 $10,230 ($71.04 /hr x 144 hrs).

12.3.11 Determination of payment (§ 423.329)

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required claims data to CMS. We estimate that on an annual basis it will take 70 stand-alone Part D plan contracts and 117 PACE contracts 52 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,724 hours**. The estimated annual cost is $690,792 ($71.04 /hr x 9,724 hr).

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

The burden associated with this requirement is the time and effort necessary for MA organizations submit the required claims data to CMS. We estimate that on an annual basis it will take 599 MA contracts 15 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **8,985 hours**. The estimated annual cost is $638,294 ($71.04 /hr x 8,985 hr).

12.3.12 Risk sharing arrangements (§ 423.336)

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors submit the required bid materials to CMS. We estimate that on an annual basis it will take 5 Part D plan sponsors 20 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **100 hours**. The estimated annual cost is $ 7,104 ($71.04 /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 912 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 **109,440 hours**. The

estimated annual cost is $7,774,618 ($71.04 /hr x 109,440 hr).

12.3.13 Retroactive adjustments and reconciliations (§ 423.343)

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

The burden associated with this requirement is the time and effort necessary for Part D only sponsors to submit the required data to CMS. We estimate that on an annual basis it will take each of the 912 Part D plan sponsors 10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,120 hours**. The estimated annual cost is $647,885 ($71.04 /hr x 9,120 hr).

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

The burden associated with this requirement is the time and effort necessary for Part only sponsors to submit the required cost data to CMS. We estimate that on an annual basis it will take each of the 912 Part D plan sponsors10 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **9,120 hours**. The estimated annual cost is $647,885 ($ 71.04/hr x 9,120 hr).

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

(f) A Part D sponsor must exclude expenditures for covered Part D drugs made by insurance or otherwise, a group health plan, or other third party payment arrangements, including expenditures by plans offering other prescription drug coverage for purposes of determining whether a Part D plan enrollee has satisfied the out-of-pocket threshold provided under §423.104(d)(5)(iii). To ensure that this requirement is met, A Part D enrollee must disclose all these expenditures to a Part D plan in accordance with requirements under § 423.32(b)(ii).

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

12.3.16 Contract provisions (§ 423.505)

(d) The Part D sponsor agrees must maintain for 10 years books, records, documents, and other evidence of accounting procedures and practices that are sufficient to meet the requirements set forth in this section.

The burden associated with this requirement is the time and effort necessary for Part D sponsors and MA organizations to maintain the required documentation outlined in this section. We estimate that on an annual basis it will take 912 respondents 52 hours for a business operations specialist to maintain the required documentation on an annual basis, for total annual burden of

47,424 hours. The estimated annual cost is $3,369,001 ($71.04 /hr x 47,424 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 912 respondents 8 hours for a business operations specialist to submit the required documentation to CMS for total annual burden of **7,296 hours**. The estimated annual cost is $518,308 ($71.04 /hr x 7,296 hr).

12.3.17 Novation agreement requirements (§ 423.552)

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

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

12.3.18 General Provisions (§ 423.562)

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

The burden associated with this requirement is the time and effort necessary for each of the 912 Part D plan sponsors to disclose the necessary information to enrollees. We estimate that it will require each of the 912 Part D plan sponsors 8 hours for a business operations specialist to disclose the information for a total annual burden of **7,296 hours**. The estimated annual cost is $518,308 ($71.04 /hr x 7,296 hr).

12.3.19 Grievance procedures (§ 423.564)

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to notify an enrollee of its decision as expeditiously as the case requires, based on the enrollee's health status, but no later than 30 days after the date the plan receives the oral or written grievance. We estimate that 912 Part D plan sponsors will provide notification of 55,334 grievance decisions. The Part D plan must provide written notification of the decision if the grievance was submitted in writing, if the enrollee requests a written response, or if the grievance relates to a quality of care issue. We estimate that the plan sponsor will have to provide written

notification to enrollees in 13,200 grievances and oral notification in 118,800 grievances. We estimate it will take 30 minutes (0.5 hours) to provide written notification for a total annual burden of **6,600 hours**. We estimate it will take 15 minutes (0.25 hours) for a business operations specialist to provide oral notification to enrollees for a total annual burden of **29,700 hours**. The total number of hours is **36,300** (6,600 + 29,700) annually. The estimated annual cost is $2,578,752 ($71.04 /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 912 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 **47,424 hours**. The estimated annual cost is $3,369,001 ($71.04 /hr x 47,424 hr).

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

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

The burden associated with this requirement is the time and effort necessary for Part D plan sponsors to document oral requests and retain the documentation in the case file. We estimate that Part D plan sponsors will receive about 3,675,000 standard coverage determination requests annually and, of that number, 1,837,500 will be oral requests. We estimate that it will take a Part D plan sponsor 3 minutes (0.05 hours) for a business operations specialist to document and retain the required documentation in the case file. Thus, we estimate that it will take 912 Part D plan sponsors a total of **91,875 hours** to perform this function on an annual basis. The estimated annual cost is $ 6,526,800 ($71.04 /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 912 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 $65,268,071 ($71.04 /hr x 918,751 hr).

12.3.21 Expediting certain coverage determinations (§ 423.570)

(c)(2) A Part D plan sponsor must document all oral requests in writing and maintain the documentation in the case file. The burden associated with this requirement is the time and effort necessary for Part D plans to maintain the required documentation outlined in this section. We estimate that on an annual basis Part D plan sponsors will receive 1,225,000 expedited coverage determination requests, of which 1,163,750 will be received orally. We estimate it will take 3 minutes (0.05 hours) for a plan sponsor's business operations specialist to document an oral request for an expedited coverage determination. Thus, it will take 912 Part D plan sponsors **58,188 hours** to perform this function on an annual basis. The estimated annual cost is $4,133,675 ($71.04 / 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 912 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 $217,596 ($71.04 /hr x 3,063 hr).

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

(a) and (c) A Part D plan sponsor must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its decision, whether adverse or favorable, as expeditiously as the enrollee's health condition requires, but no later than 24 hours after receiving the request, or, for an exceptions request, the physician's or other prescriber's supporting statement. Plan sponsors must notify enrollees in writing of favorable and unfavorable expedited coverage determinations.

The burden associated with this requirement is the time and effort necessary for each of the 912 Part D plan sponsors to disclose the necessary information to an enrollee and prescribing physician or other prescriber involved. We estimate it will take 15 minutes (0.25 hours) for a business operations specialist to provide notice of 1,212,750 expedited coverage determination decisions for a total estimated annual burden of **303,188 hours**. The estimated annual cost is $21,533,503 ($71.04 /hr x 303,118 hr).

12.3.23 Exceptions process (§ 423.578)

Exception requests must be supporting by a statement from the enrollee's prescriber and if the supporting statement is provided orally, a Part D plan sponsor may require a written follow-up. The burden associated with this requirement is the time and effort necessary for a prescribing

physician or other prescriber to submit the written supporting statement or other medical documentation to the Part D plan sponsor. We estimate 2,388,750 requests will require written documentation and that it will take the physician or other prescriber 15 minutes (0.25 hours) to provide the supporting documentation. Therefore, we estimate a total annual burden of **597,188 hours**. The estimated annual cost is $54,481,461 ($91.23/hr x 597,188 hr).

12.3.24 Administration of subsidy program (§ 423.800)

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

The burden associated with these requirements is the time and effort for the Part D plan sponsor offering the Part D plan to provide information to CMS and to maintain documentation. We estimate that it will take each of the 912 respondents approximately 52 hours for a business operations specialist to provide the information to CMS. We also estimate that it will take approximately 26 hours for each of the 912 respondents to maintain the information for tracking purposes. Therefore, we estimate a total annual burden of **71,136 hours** to comply with these requirements. The estimated annual cost is $5,053,501 ($71.04 /hr x 71,136 hr).

12.3.25 Change in Ownership (§ 423.892)

(c) A sponsor who is contemplating or negotiating a change of ownership must notify CMS. We estimate that approximately 1 percent of sponsors will fall into this category in a given year.

The burden associated with this requirement is the time and effort necessary for a sponsoring entity to submit the required notification to CMS. On an annual basis it will take 50 entities (1 percent of 5,000) about 1.0 hour for a business operations specialist to submit the required notification to CMS, for a total of approximately **50 hours**. The estimated annual cost is $ 3,552 ($71.04 /hr x 50 hr).

12.3.26 Burden Summary

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 (all respondents)
423.32(d)		912	3	2	1,514	4,542
	R		0.017 (1 min)	4,986	3,954,000	67,218
423.36(b)	R	912	1.017	32,401	1,903,752	33,121

423.46(b)	R	912	0.25	4,542	3,954,000	988,500
423.104(g)	R	912	10	1	912	7,570
423.120(d)	R	634	1	1	634	634
423.153(b)	R	912	0.5	1	912	378.5
423.153(c)	R	912	0.5	1	912	378.5
423.153(f) (Disclosure to CMS, rule and non-rule)	R	1	0.0167	22,516		376
423.168 (c) 423.171 (a), 423.904(a)	R	12	1	12	144	144
423.329(b)	R	187	52	1	187	9,724
		599	15	1	599	8,985
423.336(a)	R	5	20	1	5	100
423.336(c)	R	912	10/month	12	9,516	95,160
423.343(c)	R	912	10	1	912	7,570
423.343(d)	R	912	10	1	912	7,570
423.578(a) and (b)	R		0.25		2,388,750	597,188
423.800(b)	R	912	78	1	912	59,046
423.892(c)	R	50	1	1	50	50
Subtotal (Reporting)		*10,607*	*varies*	*varies*	*12,217,693*	*1,888,255*
CFR Section	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.46(d)	RK	912	0.083 (5 min)	4,542	3,954,000	328,182
423.120(b)	RK	912	2	1	912	1,514
423.128 (e)(5)	RK	288	160	1	288	15,733

423.153(f) (Upload notice into claims system)	RK	219	5	1	219	1,095
423.153(f) (Creating DMP, rule and non-rule)	RK	209	80	1	209	16,720
423.153(f) (Conduct Case Management, rule and non-rule)	RK	1	5	22,516	5	112,580
423.505(d)	RK	912	52	1	912	39,364
423.505(f)	RK	912	8	1	912	6,056
423.564(g)	RK	912	52	1	912	39,364
423.568(a)(3)	RK	912	0.05 (3 min)	2,317	1,837,500	91,875
423.570(c)(2)	RK	912	0.05 (3 min)	1,467.50	1,163,750	58,188
423.570(d)	RK	912	0.25	15.4	12,250	3,063
Subtotal (Record keeping)		7,801	*Varies*	*Varies*	*6,971,869*	*713,734*
423.34(e)	TPD	912	0.25	164	130,000	32,500
423.44(b)	TPD	912	1	1	912	912
			0.1 (6 min)	626	496,344	49,634
			1	1	912	912
			0.017 (1 min)	1.4	1,100	18.7
			1	1	912	912
			0.1 (6 min)	22	17,772	1,777
423.48	TPD	912	2	1	912	1,514
423.128(a)	TPD	912	200	1	912	151,400
423.128(e)	TPD	912	160	1	912	121,120
423.128(e)(5)	TPD	288	160	n/a	288	145, 920

423.153(f) (Send second notice, or alternative second notice)	TPD	219	0.083	17.4	3,692	307
423.153(f) (Send Initial Notice, non-rule)	TPD	219	0.0833	1	1,118	93
423.153(f) (Transfer of Case Management Information)	TPD	11	1	1	1	11
423.562(a)	TPD	912	8	1	912	6,056
423.564(e)	TPD	912	0.5	16.6	13,200	6,600
			0.25	149.8	118,800	29,700
423.568(b), (c), (d), and (f)	TPD	912	0.25	1436.6	1,139,250	284,813
			0.25	3,197.70	2,535,750	633,938
423.572(a) and (c)	TPD	912	0.25	1,529.30	1,212,750	303,188
Subtotal (Third Party Disclosure)		6,209	*varies*	*7,169.8*	*5,676,449*	*1,771,326*

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

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

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

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

The burden associated with the requirement on State agencies to inform CMS of cases where eligibility is established or redetermined is estimated to total approximately **6,120 annual hours**. We estimate that there will be approximately 600,000 of these cases on an annual basis. We also estimate that it will take approximately 10 hours per month for the State agency to inform CMS of these cases.

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

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

The burden associated with the requirement on States to provide CMS with other information as specified by CMS is estimated to total approximately **1,020 annual hours**. Based on the experience to date, it will take on average 20 hours per State on an annual basis to provide CMS with the specified information.

12.4.2 Requirements (§ 423.910)

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

The burden associated with the requirement on States to submit an electronic file identifying each full benefit dual eligible enrolled in the State for each month with Part D drug coverage is estimated to total approximately 120 hours per State on an annual basis. We estimate that it will take approximately 10 hours for each State's business operations specialist to submit an electronic file on a monthly basis. Therefore, we estimate a total burden of **6,120 hours** on an annual basis. The estimated annual cost is $434,765 ($71.04 /hr x 6,120 hr).

Burden Summary (States: Subtotal)

CFR Section	Response Type*	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
423.904(b)	R	51	10/month	12,000	600,000	6,120
	R		20	1	51	1,020
423.910(d)	R	51	10/month	12	51	6,120
Subtotal		**51**	**Varies**	**varies**	**600,102**	**13,260**

*R (reporting).

12.5 ICRs Regarding the Part D Sponsor's System Programming (§ 423.120(c)(6)) (No Changes)

For this provision the burden will include the time and effort for Part D adjudication systems to be programmed for the model notices. We estimate that it will take sponsors and PBMs with Part D adjudication systems approximately 93,600 hours in 2019 for software developers and programmers to program their systems to comply with the requirements of § 423.120(c)(6). The sponsors and PBMs will need approximately six to twelve months to perform system changes and testing. The total hour figures are based on a 6-month preparation and testing period. There are roughly 1,040 full-time working hours in a 6-month period. Using an estimate of 3 full-time Software Developers and Programmers at $98.54 /hr amounts to **93,600 hours** (3 workers x 1,040 hr x 30 sponsors/PBMs) at a cost of **$9,403,056** (93,600 hr x $ 100.46/hr) for 2019. This is a one-time burden. There will be no burden associated with 2020 and 2021.

Burden Summary (Private Sector: Subtotal)

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

*RK (recordkeeping).

12.6 ICRs Regarding the Creation of Model Notices to the Medicare Beneficiaries and Prescribers (§ 423.120(c)(6)) (No Changes)

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

For this provision the burden will include the time and effort for creating the model notices. We estimate that 212 parent organizations will need to create two model notices to notify beneficiaries and prescribers under finalized § 423.120(c)(6). We project that it will take each organization 3 hours at $71.04 /hr for a business operations specialist to create the two model notices. In aggregate, we estimate a one-time burden of **636 hours** (212 organizations x 3 hr) at a cost of **$44,698** (636 hr x $71.04 /hr)or $207.84 per organization ($44,698 /212 organizations) in 2019. There will be no burden associated with 2020 and 2021.

Burden Summary **(**: Subtotal)

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

Subtotal	**212**	**3**	**1**	**212**	**636**

*RK (recordkeeping).

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

For this provision we estimate that it will take an average of 5 minutes (0.083 hr) at $39.22/hour for an insurance claim and policy processing clerk to generate and disseminate the aforementioned notice. We estimate that an average of approximately 800 prescribers will be on the Preclusion List in early 2019 with roughly 80,000 Part D beneficiaries affected; that is, 80,000 beneficiaries will received prescriptions written by these prescribers and will therefore receive the notice referenced in § 423.120(c)(6). In aggregate, we estimate a burden of **6,640 hours** (0.083 hr/response x 80,000 responses) at a cost of **$269,053** (6,640 hr x $ 40.52/hr) or $1,269 per organization ($269,053 / 212 organizations) for an insurance claim and policy processing clerk to prepare and distribute the notices in 2019.

In 2020 and 2021, we estimate that roughly 150 prescribers will be added to the Preclusion List, though this will be largely offset by the same number of prescribers being updated to reflect a change in their preclusion status (for example, based on reenrollment after the expiration of a reenrollment bar) with 15,000 affected beneficiaries. In aggregate, we estimate an annual burden of **1,245 hours** (15,000 beneficiaries x 0.083 hr) at a cost of **$50,447** (1,245 hr x $40.52 /hr) or $336.31 per prescriber ($50,447 /150 prescribers).

Burden Summary (Private Sector: Subtotal)

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

*TPD (third party disclosure).

- SUMMARY OF REQUIREMENTS AND ANNUAL BURDEN ESTIMATES

Total Annual Burden Estimates

ICR Section	# Respondents	Time (hr per response)	# Responses (per respondent)	Total Responses (all respondents)	Total Annual Time (all respondents)
12.1. Business Continuity Plans (No Change)	99	Varies	1	99	15,920
12.3. Medicare Prescription Drug Benefit Program: Plans (Revised)	912	Varies	Varies	616,933,733	9,178,691

12.5. System Programming (No Change)	30	3,120	1	30	93,600
12.6. Creation of model notices (No Change)	212	3	1	212	636
12.7 Preparation and issuance of model notices (No Change)	950	0.083 (5 min)	Varies	95,000	7,885
Subtotal (Private Sector)	*2,203*	*Varies*	*Varies*	*617,029,074*	*9,296,732*
12.2. Medicare Prescription Drug Benefit Program: Bene (Revised)	11,736,619	Varies	1	11,736,619	3,003,602
Subtotal (Individuals and Households)	*11,736,619*	*Varies*	*1*	*11,736,619*	*3,003,602*
12.4. State Eligibility Determinations (No Change)	51	Varies	Varies	600,102	13,260
Subtotal (States)	*51*	*Varies*	*Varies*	*600,102*	*13,260*
TOTAL	**11,738,873**	**Varies**	**Varies**	**629,365,795**	**12,313,594**

The revisions associated with the Medicare Prescription Drug Benefit Program (PLAN) includes the Part D sponsor's system programming of the Preclusion List, creation of model notices to be issued to Medicare beneficiaries and prescribers when a prescriber is identified on the Preclusion List, and preparation and issuance of model notices to the Medicare beneficiaries and prescribers. The system programming and creation of model notices is a one-time burden and is not considered an annual burden.

- INFORMATION COLLECTION INSTRUMENTS, INSTRUCTIONS AND GUIDANCE DOCUMENTS

Attachments 1a and 1b - 2019 Compensation Certification (Nonsubstantive change divides active attachment 1 into attachments 1a and 1b)
(See section 12.1, Business Continuity Plans.)

1a – Compensation Certification to be Completed by All Organizations
1b – Compensation Certification to be Completed by Any Organization with Renewal Commission

Attachments 2a and 2b – Structure Submission Form (Nonsubstantive change divides active attachment 2 into attachments 2a and 2b)
(See section 12.1, Business Continuity Plans.)

2a – Compensation Structure for Plans

2b – Compensation Structure for Writing Agents

Attachment 3 – Covered Agent Information Sheet (No Changes)
(See section 12.1, Business Continuity Plans.)

Attachment 4 - 2019 Compensation Structure for Writing Agents by Contract/PBP Number (No

Changes)
(See section 12.1, Business Continuity Plans.)

Attachments 5a – 5c – Instructions (Nonsubstantive change divides active attachment 5 into attachments 5a, 5b, and 5c)
(See section 12.1, Business Continuity Plans.)

5a – Instructions for MA and PDP Organizations
5b – Instructions for Writing Agents
5c – Compensation Workbook

Attachments 6a – 6f – Drug Management Program Model Notices (Adds new documents, attachments 6e and 6f)
(See section 12.6, Creation of Model Notices.)

6a – Instructions for Drug Management Program Notices (No Changes)

6b – Initial Notice Sent to Potentially At-Risk Beneficiaries (No Changes)
6b - Crosswalk for Initial Drug Management Program Notices

6c – Second Notice Sent to Beneficiary Designating At-Risk Status (No Changes)
6c – Crosswalk for Second Drug Management Program Notices

6d – Alternate Second Notice Sent to Beneficiary Not Considered At-Risk (No Changes)
6e – Sample Prescriber Inquiry Letter (New)
6f – Sample Beneficiary Transfer Letter (New)

Attachment 7 – Precluded Provider Model Notice (New)No Changes)
(See section 12.7, Preparation and Issuance of Model Notices.)

Attachment 8a – 8g (see section 12.3, Medicare Prescription Drug Benefit Program: Plans) – Part D Explanation of Benefits (No changes)

8a- 2020 Model Part D Explanation of Benefits
8b – Exhibit A: Example Cover Page of the Model Part D EOB
8c - Exhibit B: Examples of Section 1 (the List of Prescriptions)
8d - Exhibit C: Example of Section 2 (Drug Payment Stages)
8e - Exhibit D: Example of Section 3 (Amounts and Definitions for TrOOP and Total Drug Costs)
8f - Exhibit E: Example of Section 4 (Changes to the Formulary)
8g - Exhibit G: Example of Sections 5 and 6 (Information for Reference)
8h - Exhibit H: Example of a Part D EOB (All Sections Included)

- ICRS EXEMPT FROM THE REQUIREMENTS OF THE PRA

(No Change)

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

In § 423.507(a), if a Part D sponsor does not intend to renew its contract, it must notify CMS in writing by the first Monday of June in the year in which the contract ends and notify, in an manner that meets the requirements of this section, each Medicare enrollee, at least 90 days before the date on which the nonrenewal is effective.

In § 423.508(b), if the contract is terminated by mutual consent, the Part D sponsor must provide notice to its Medicare enrollees and the general public as provided in paragraph (c) of this section.

In § 423.509(b), if CMS notifies the Part D sponsor in writing 90 days before the intended date of their termination the Part D plan sponsor must notify its Medicare enrollees of the termination by mail at least 30 days before the effective date of the termination. The Part D sponsor must also notify the general public of the termination at least 30 days before the effective date of the termination by publishing a notice in one or more newspapers of general circulation in each community or county located in the Part D sponsor's service area.

In § 423.510(a), if a Part D sponsor terminates its contract because CMS fails to substantially carry out the terms of the contract the Part D sponsor must give advance notice to CMS, its Medicare enrollees, and the general public in a manner that meets the requirements set forth in the section.

In § 423.551(c), states that a Part D plan sponsor that has a Medicare contract in effect under § 423.502 of this part and is considering or negotiating a change in ownership must notify CMS at least 60 days before the anticipated effective date of the change. The Part D plan sponsor must also provide updated financial information and a discussion of the financial and solvency impact of the change of ownership on the surviving organization.

In § 423.552(a), Part D plan sponsors are required to submit to CMS, at least 30 days before the proposed change of ownership date, 3 signed copies of the novation agreement containing the provisions specified in this section, and 1 copy of other relevant documents required by CMS.

In § 423.859(c), states that CMS may waive or modify the requirements of this part if an entity seeking to become a prescription drug plan in an area such, as a territory, other than the 50 States or the District of Columbia requests waiver or modification of any Part D in order to provide qualified prescription drug. The burden associated with this requirement is the time and effort for the Part D plan to make a request of waiver or modification to CMS. We estimate that approximately 2 Part D plans will request a waiver or modification on an annual basis.

Section 423.863(a) discusses the process CMS uses for the solicitation and approval of bids. CMS solicits bids from eligible fallback entities for the offering in all fallback service areas in one or more Part D plan regions of a fallback prescription drug plan. CMS specifies the form and manner in which fallback bids are submitted in separate guidance to bidders. The burden associated with this requirement is the time and effort for the fallback entities to prepare and submit a bid that meets the requirements of the section and related sections. We estimate fewer than 10 fallback entities will submit a bid every three years.

Section 423.863(b) discusses the procedures CMS uses to enter into contracts. CMS solicits bids from eligible fallback entities and uses competitive procedures to enter into contracts. The burden associated with this requirement is the time and effort for the fallback

entities to enter into a contract with CMS that meets the requirements of this section and related sections. We estimate, as an upper limit, that approximately 5 fallback entities will enter into a contract with CMS on an annual basis.

Section 423.871(f) states that each contract for a fallback prescription drug plan requires an eligible fallback entity offering a fallback prescription drug plan to provide CMS with the information CMS determines is necessary to carry out the requirements of this section. The burden associated with this requirement is the time required of the fallback prescription drug plan to provide CMS with the information CMS determines necessary. We estimate that approximately 5 fallback prescription drug plans will enter into a contract with CMS.

Section 423.907(a) discusses the requirements on territories to submit plans for approval by the Secretary to receive increased grants. This paragraph states that a territory may submit a plan to the Secretary under which medical assistance is to be provided to low-income individuals for the provision of covered Part D drugs. Paragraph (b) describes what a plan must include. The burden associated with this requirement is the time and effort of territories to prepare and submit a plan for approval. We estimate that this requirement will affect 5 territories.

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

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

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

In § 423.584, the requirements under Expediting Certain Redeterminations.

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

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

In § 423.756(a), CMS will allow the Part D plan sponsor to provide evidence that it has not committed an act or failed to comply with the requirements as described. In addition, CMS may allow additional time for the Part D plan sponsor to provide the evidence if the Part D plan sponsor sends a written request providing a credible explanation of why additional time is necessary.

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

In § 423.132(a), a Part D sponsor must require a pharmacy that dispenses a covered Part D drug to inform an enrollee of any differential between the price of that drug and the price of the lowest priced generic version of that covered Part D drug that is therapeutically equivalent and bioequivalent and available at that pharmacy, unless the particular covered Part D drug being purchased is the lowest-priced therapeutically equivalent and bioequivalent version of that drug available at that pharmacy. Since the information must be provided after the requirements will be incurred by pharmacies duringdrug is dispensed at the normal coursepoint of their business

practices, we believe they are exempt fromsale or, in the PRA.

case of dispensing by mail order, at the time of delivery of the drug. The burden associated with this requirement is the time and effort necessary for the Part D sponsor to notify the pharmacy of the disclosure requirement referenced in this section and the burden on a pharmacy to provide the necessary disclosure to the enrollee.

In § 423.136(c) and (d), for any medical records or other health and enrollment information it maintains with respect to enrollees, a Part D plan sponsor must maintain the records and information in an accurate and timely manner and provide timely access by enrollees to the records and information that pertain to them. The burden associated with this requirement is the time and effort necessary to maintain and disclose enrollee records.

Section 423.904(d) requires States to make available low-income subsidy application forms, information on the nature of, and eligibility requirements for the subsidies under this section, and offer assistance with the completion of the application forms. States must require an individual or personal representative applying for the low-income subsidy to complete all required elements, provide documents as necessary, and certify as to the accuracy of the information provided. In addition, States must provide CMS with other information as specified by CMS that may be needed to carry out the requirements of the Part D prescription drug benefit.

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

Section 423.505(k)(5) states that the Chief Executive Officer, Chief Financial Officer, or an individual delegated the authority to sign on behalf of one of these officers, and who reports directly to the officer, must certify that the information provided is accurate, complete, and truthful and fully conforms to the requirements in §§ 423.336 and 423.343 and acknowledge that this information will be used for the purposes of obtaining Federal reimbursement.

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 2019 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/2019/DCB_h.pdf) multiplied by the number of burden hours (20).

15. Changes to Burden

Non-rule Changes

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 was associated with CMS-4182-F included burden for the DMP provisions associated with the modifications adopted to comply with CARA, as described in section 12. Provisions that codified existing guidance and Part D sponsor practice, were not separately accounted for at that time, as they were accounted for generally as part of Part D sponsor drug utilization management activities required under § 423.153(b).

This revision captures the requirement that Part D sponsors send an initial notice to the subset of PARBs for whom the sponsors intend to implement a coverage limitation, based on the outcomes of case management. As described in section 12, the PRA package revision associated with CMS 4182-F only quantified burden associated with sending the second notice (or alternate second notice). This revision captures the burden associated with Part D sponsors' required reporting back to CMS on the outcomes of case management (in OMS) or coverage limitations (in MARx) which had previously not been separately quantified. Lastly, this revision separately quantifies the burden associated with transfer of beneficiary information between sponsors when a PARB or ARB switches Part D plans.

Summary for Non-Rule Changes Associated with 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 (Creating DMP)	RK	209	209	80.00	16,270	476.04	7,959,389	0
§ 423.153 (Conduct Case Management)	RK	209	22,358	5.00	22,358	108.492**	12,128,321	12,128,321
Subtotal (Recordkeeping)		*209*	*22,567*	*Varies*	*38,628*	*Varies*	*20,087,710*	*12,128,321*

Proposed Rule (CMS-4190-P) Changes

ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)

As discussed in section III.A. of this rule, we propose to codify the statutory requirement that Part D plan sponsors establish DMPs by 2022. We also propose that, beginning in 2021, DMPs evaluate enrollees with a history of opioid-related overdose as potential at-risk

beneficiaries (PARBs) that CMS reports to sponsors through the Overutilization Monitoring System (OMS).

As brief background on DMPs for context for this section, in general, the DMP requirements are codified at § 423.153(f). These provisions require Part D sponsors to conduct case management of PARBs identified by OMS through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and benzodiazepines.[2] After case management is completed, if a plan sponsor intends to limit a beneficiary's access to coverage of opioids and benzodiazepines, the sponsor must provide an initial written notice to the beneficiary and their prescribers. After the beneficiary has a 30-day time period to respond, the plan sponsor sends a second notice to the beneficiary, if the sponsor determines the beneficiary is an at-risk beneficiary (ARB), that the sponsor is implementing a coverage limitation on opioids and/or benzodiazepines, or an alternative second notice if the plan sponsor determines that the beneficiary is not an ARB. Thus, every beneficiary who receives an initial notice receives a second or alternate second notice.

In 2019, a CMS analysis found that a majority of Part D contracts (669 of 779), or 85.9 percent) voluntarily included a DMP. Our proposal to codify the requirement that sponsors adopt DMPs would only affect the remaining minority of sponsors currently not offering such programs. There are 111 contracts (plan sponsors) run by 79 parent organizations that would be involved. Furthermore, we estimate that only 158 additional PARBs will be identified by these 111 contracts due to meeting the minimum OMS criteria. We estimate burden at the parent organization level because we believe that is a closer reflection of the number of systems that will need to be updated versus the contract level.

The estimated reporting burden to these sponsors has four aspects. Under § 423.153(f), sponsors must: (1) design a DMP; (2) conduct case management, which includes sending written information about PARBs to prescribers; (3) program and issue written notices to PARBs and ARBs; and (4) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

For one-time initial development, we estimate it will take each parent organization without a DMP 80 hours for a team of clinical and non-clinical staff to design its DMP. Thus, we estimate 6,320 hours (79 parent organizations* 80 hr) program-wide for all remaining parent organizations to develop DMPs consistent with the requirements of §423.153(f). We solicit comment as to the accuracy of these estimates.

We estimate that development will likely require two pharmacists (working at $118.90/hr) and two general operation managers (working at $119.12/hr) per organization. Thus, the hourly wage for the organization's development team is $476.04 [2 pharmacists * $118.90/hr] + [2 managers * $119.12/hr]. The labor rates for the development team is summarized in the following table.

Labor Rates for the Development Team

Occupation	Adjusted Hourly Wage ($/hr)	Number of Staff	Total Wages ($/hr)
General operations manager	119.12	2	238.24
Pharmacist	118.90	2	237.80

2 CMS currently designates both opioids and benzodiazepines as "Frequently Abused Drugs" for purposes of DMPs. See "Part D Drug Management Program Policy Guidance", November 20, 2018, p. 6; https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/2019-Part-D-Drug-Management-Program-Policy-Guidance-Memo-November-20-2018-.pdf

TOTAL	238.02	4	476.04

Therefore, each of the 79 parent organizations affected by this proposal will spend 80 hours at a cost of $38,083 (80 hr * $476.04/hr) for the team of four professionals to develop the DMP. The aggregate burden will therefore be 6,320 hours (79 parent organizations * 80 hr) at a cost of $3,008,573 (6,320 hr * $476.04/hr).

Once a DMP is developed and in place, the primary operations for impacted sponsors will involve case management by the sponsor to assess those enrollees reported as PARBs by CMS's OMS. The 111 contracts run by 79 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. They enroll only 410,000 Part D beneficiaries (less than 1 percent of total Part D enrollment in 2019). Accordingly, based on analysis of the first 3 quarters (January, April, and July 2019) of the OMS report data, we found that only 127 beneficiaries (about 0.7 percent) who met the minimum OMS criteria were not reported thus far in 2019 by CMS to the sponsors, because the sponsors did not have a DMP. Using this estimate, we can project that annually that about 158 beneficiaries would not be reported to their plan sponsors due to not having a DMP until DMPs become mandatory no later than January 1, 2022.

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. 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 $118.90/hr, 2 hours would be conducted by a health technician ("Technician, All other") at $50.90/hr, and 1 hour would be conducted by a physician at $202.86/hr to work directly with providers on discussing available options and determining the best course of action. In aggregate, we estimate an annual burden for an estimated 158 enrollees annually newly subject to case management under this proposal to cost $85,708.68 per year (158 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

The 79 Part D parent organizations affected by this proposal also would have to upload beneficiary notices into their internal claims systems before they could issue them. We estimate that it will take each, on average, 5 hours at $86.14/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 estimate a one-time burden of 395 hours (5 hr * 79 sponsors) at a cost of $34,025 (395 hr * $86.14/hr).

Since currently 5 percent of PARBs receive an initial and second notice (or alternate second notice), we estimate that 8 beneficiaries (158 beneficiaries * 0.05) would receive an initial notice and 8 would receive a second notice (or alternate second notice). Since fewer than 10 beneficiaries are affected by this, the burden of sending these notices is exempt from PRA.

As to disclosure of DMP case management outcomes data to CMS pursuant to § 423.153(f)(15), as stated earlier, the plan sponsors newly impacted by a mandatory DMP policy would 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 sponsors on average 1 minute (0.0167 hr) to report this information to OMS and MARx. In aggregate, we estimate an annual burden of 2.6386 hours (158 newly identified PARBs annually * 0.0167 hr) at

a cost of $134 (2.6386 hr * $50.90/hr).

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 (DMP: Upload model notices)	RK	79	79	5	395	86.14	34,025	0
§ 423.153 (DMP: Disclosure to CMS)	R	79	158	0	3	50.90	134	134
§ 423.153 (DMP: Creating DMP (those without DMPs))	R	79	79	80	6,320	476.04	3,008,573	0
TOTAL		**79**	**316**	**Varies**	**6,718**	**Varies**	**3,043**	**134**

*R (reporting) and RK (recordkeeping).

ICRs Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)

Our proposal under § 423.100 to identify and report beneficiaries with a history of opioid-related overdose through OMS to Part D plan sponsors would mean that additional beneficiaries would be reported by OMS as PARBs. Based on July 2017 through June 2018 opioid-related overdose data, CMS's internal analysis estimates that about 18,268 enrollees meet the proposed criteria of an opioid-related overdose and would be PARBs. We project using this one-year estimate that in 2021 about 18,268 additional PARBs with an opioid-related overdose would be identified and reported by OMS. The estimated reporting burden associated with these new PARBs has three of the four aspects of the burden we estimated for mandatory DMPs, as previously described. Under § 423.153(f), sponsors must: (1) conduct case management, which includes sending written information about PARBs to prescribers; (2) issue written notices to PARBs and ARBs; and (3) disclose data to CMS about the outcome of case management via OMS and about any coverage limitation information into MARx.

The assumptions surrounding case management by plan sponsors in the previous section were applied to the estimated population of 18,268 PARBs projected to be identified annually under this proposal. In aggregate, we estimate an annual burden for a projected 18,268 enrollees annually newly subject to case management, including sending the required written information to the prescribers of PARBs, under this proposal to cost $ 9,909,659.28 per year (18,268 enrollees * ([2 hr * $118.90/hr for Pharmacists] + [2 hr * $50.90/hr for Technicians, All other] + [1 hr * $202.86/hr for Physician]).

In order to estimate the impact of providing beneficiary notices, we compare two populations: (1) Part D beneficiaries projected to be potentially at-risk, by meeting the OMS criteria (which CMS estimates as 22,516 PARBs, based on internal data); and (2) beneficiaries with a history of opioid-related overdose (which CMS estimates as 18,268 PARBs, based on internal data).

We believe the population of beneficiaries with a history of opioid-related overdose would have a much higher rate of coverage limitations imposed by sponsors, due to the history of overdose being the risk factor most predictive for another overdose or suicide-related event.[3] We estimate that about 47.5 percent or 8,677 beneficiaries (18,268 beneficiaries * 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.

This is in contrast to the PARBs meeting minimum and supplemental OMS criteria, where Part D program experience demonstrates a significantly lower incidence of coverage limitations (that is, only about 1,126 or 5 percent of the 22,516 beneficiaries receive notices).[4]

Following these assumptions, of the 40,784 (22,516 PARBs + 18,268 PARBs) Part D beneficiaries projected to be potentially at-risk, either by meeting the OMS criteria (22,516 PARBs) or the history of opioid-related overdose as defined (18,268 PARBs), those receiving a first notice from their plan sponsor informing them of the sponsor's intention to apply a coverage limitation are projected to total 9,803 enrollees (8,677 with history of opioid-related overdose + 1,126 meeting OMS minimum and supplemental criteria), or 24 percent of PARBs (40,784 * 0.24).

We estimate it would take 10 minutes (0.1667 hr) at $50.90/hr for a health technician to send two notices (each notice would require 5 minutes). In aggregate, we estimate an annual burden of 1,446 hours (8,677 enrollees * 0.1667 hr) at a cost of $73,601 (1,446 hr * $50.90/hr).

Evaluation of the use of POS claim edits under OMS since 2013 does not demonstrate a steady increase or decrease in edits. The OMS and POS edit reporting systems commenced in 2013 and 2014, and then between 2015 and 2018 the number of beneficiaries with opioid POS claim edits only ranged from 1,152 to 1,351 annually. As such, given that the vast majority of Part D enrollees are in a plan already offering a DMP, including the majority of Part D enrollees with a history of opioid-related overdose, we do not anticipate major shifts in the baseline average number of annual POS edits (and related initial notices). This stability in the annual number of ARBs and related notices to date appears largely unaffected by the baseline population of identified PARBs. However, we recognize that this proposed change is projected to approximately double the number of beneficiaries CMS identifies to sponsors as PARBs and accordingly solicit comment as to whether including beneficiaries with a history of opioid-related overdose and the projected doubling in identified PARBs is expected to require significant modifications by sponsors to respond to this increase in case management volume.

Model beneficiary notices[5] provided by CMS, as well as the required written information sent by sponsors to prescribers of PARBs as part of the case management process, would need to be revised to incorporate language specific to a PARB having a history of opioid-related overdose. For the model beneficiary notices, this includes updates to the sections defining DMPs and possible justifications for applying a coverage limitation. Proposed changes to the model

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3 Bohnert KM, Ilgen MA, Louzon S, McCarthy JF, Katz IR. Substance use disorders and the risk of suicide mortality among men and women in the US Veterans Health Administration. Addiction. 2017 Jul; 11/2(7):1193-1201. doi: 10.1111/add.13774.

4 CMS' internal analysis estimates that about 22,516 PARBs would meet the current OMS criteria based on 2018 data. An additional 18,268 PARBs are projected annually to meet the proposed criteria of opioid-related overdose.

5 Notice documents available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Drug-Management-Program-Notices-.zip

beneficiary notices are included in this information collection request. Additionally, sponsors may need to update their DMP prescriber written communications to include history of opioid-related overdose as a possible reason for a beneficiary meeting the OMS criteria. The changes needed to align the model beneficiary notices and the written communication are expected to be minimal.

We estimate it would take no more than 1 hour at $50.90/hr for a health technician to draft and implement such changes. In aggregate, we estimate a one-time burden of 288 hours (288 parent organizations * 1 hr/response) at a cost of $14,659 (288 hr * $50.90/hr).

With respect to the burden of disclosure of DMP data to CMS associated with the increase in PARBs, we estimate that it will take sponsors on average 1 minute (0.0167 hr) at $50.90/hr for a health technician to document OMS and/or MARx the outcome of case management and any applicable coverage limitations. In aggregate, we estimate an annual burden of 305 hours (18,268 PARBs * 0.0167 hr) at a cost of $15,525 (305 hr * $50.90/hr).

The following table summarizes the DMP provisions for which impact is discussed in sections IX.B.3. and IX.B.4. of the proposed rule.

Summary for Mandatory DMPs and Identification of Additional PARBs

Regulatory Citation (Subject)	Response Type*	Number of Respondents	Total 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 (Conduct Case Management)	R	79	158	1	158	542.46	85,709	85,709
§ 423.153 (Disclosure to CMS)	R	79	158	0.0167	2.6386	50.90	134	134
§ 423.100 (Revise Model Notices)	R	288	288	1.00	288.0	50.90	14,659	0
§ 423.100 (Conduct Case Management)	R	288	18,268	1	18,268	542.46	9,909,659	9,909,659
§ 423.100 (Disclosure to CMS (newly identified PARBs))	R	288	18,268	0.0167	305	50.90	15,525	15,525
Subtotal (Reporting)		*288*	*37,140*	*Varies*	*19,022*	*Varies*	*10,025,686*	*10,011,027*
§ 423.153 (Creating DMP (those without DMPs))	RK	79	79	80.00	6,320.0	476.04	3,008,573	0
§ 423.153 (Upload Model Notices)	RK	79	79	5.00	395.0	86.14	34,025	0
Subtotal (Record keeping)		*79*	*158*	*Varies*	*6,715*	*Varies*	*3,042,598*	*0*
§ 423.100 (Send Model Notices)	TPD	288	8,677	0.1667	1446	50.90	73,601	73,601

TOTAL	**288**	**45,975**	**Varies**	**27,183**	**Varies**	**13,141,885**	**10,084,628**

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

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

In this rule, we are proposing under § 423.128 to require Part D sponsors to disclose, beginning 2021, information about the risks of prolonged opioid use to enrollees. In addition to this information, Part D sponsors of MA-PDs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Part C. Part D sponsors of PDPs must disclose coverage of non-pharmacological therapies, devices, and non-opioid medications under their plans and under Medicare Parts A and B.

Before Part D sponsors can send this information, they would have to create and upload materials into their internal systems. Based on 2019 CMS data, there are 608 Part D legal entities (sponsors) with which CMS contracts, associated with 288 parent organizations that these contracts identified in their initial applications, which is confirmed annually. Based on our knowledge of the way parent organizations and their Part D legal entities are structured, we believe it is appropriate to estimate burden at the parent organization level, as it is a closer reflection of the number of systems that will need to be updated versus at the contract level.

We estimate that 288 Part D sponsors would be subject to this proposal, based on 2019 data. We estimate that it will take on average 2 hours at $86.14/hr for a computer programmer to upload the information into the systems. This would result in a one-time burden of 576 hours (2 hr * 288 parent organizations) at a cost of $49,617 (576 hours * $86.14/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.

We also estimate a one-time burden of 2 hours at $118.90/hr for a pharmacist to develop the materials(s) to be sent to the beneficiaries. In aggregate, we estimate a one-time burden of 576 hours (288 parent organizations * 2 hr) at a cost of $ 68,486 (576 hr * $118.90/hr). Although there might be the need for updates in future years (if opioid risk and/or coverage information changes), we believe the burden to making such updates to existing materials will be negligible as the changes will be minor and may only occur in some future years. Hence, the more accurate approach adopted here is to estimate this as a one-time update.

We propose that Part D sponsors may disclose the opioid and coverage 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 notification.

There are several Part D enrollee groups presented in section III.D. of this proposed rule that we suggest could be sent the required information and thus, several approaches to estimate

the burden. These enrollee group estimates range from sending the information to 46,759,911 enrollees to 2,698,064 enrollees, Therefore, for plans convenience and planning, Table J8 presents an alternative cost analysis of the wide range of alternatives discussed in section III.D. of this proposed rule.

We also include calculations under assumption that only 50 percent want paper and calculations under assumption that 75 percent want paper. As can be seen, the range of costs are $0.1 to $0.5 million (for sending notices by paper to all Part D enrollees. Thus, cost need not be a factor in plan choice.

Since the range of costs are $0.1 million to $0.5 million, for purposes of the Table J8, we are listing the $0.1 million or $118,103 first year cost ($68,486 for creation of materials + $49,617 for system updates) but leaving out mailing costs until we receive feedback from our stakeholders. We however, solicit stakeholder feedback on which alternatives they believe are most likely and unlikely, as well as stakeholder feedback on our estimation of printing and delivery costs.

In making estimates on the burden of sending out notices, we assume that the IT systems of the plan would generate and mail the documents once a template is produced. Thus, the only costs per enrollee are paper, toner, and postage. We also assume 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. Thus cost for one page is 2.50/500 = $0.005
- Cost of toner: Toner costs can range from $50 to $200 and each toner can last 4,000 to 10,000 sheets. CMS assumes a cost of $50.00 for 10,000 pages. Thus cost per page is $50/10,000 = $0.005
- Cost of postage: For 2019, the bulk postage rates are $0.19 per 200 pages. Thus the cost per page is 0.19/200 = 0.000950.

Thus, the aggregate cost per page is 0.01095 (0.005 + 0.005 + 0.000950). This per page amount is multiplied by the number of enrollees receiving the notification. Note that mailing costs are annual while the programming updates and the development of materials are first-year costs with minimal or no costs in future years. The product of the cost per page times the number of enrollees plus the first year costs are the costs listed for each possibility in Table J8

Table J8: Impacts of Several Alternatives for Providing Information to Opioid Users

(A) Issue	(B) Number of Opioid Users in this Category	(C) Number of Part D Sponsors	(D) Percentage of Enrollees Wanting Paper Delivery	(E) Cost per Plan or Enrollee for Paper Copies	(F) Aggregate Cost (B)*(D)*(E)	(G) Total Cost for this Scenario	Total Cost Rounded (millions)
2 hours of programming	N/A	288	N/A	172.28	49,617	N/A	N/A
2 hours for a pharmacist to develop the materials	N/A	288	N/A	237.8	68,486	N/A	N/A
Total first year programming and development cost	N/A	N/A	N/A	N/A	118,103	N/A	N/A
75% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	75%	0.01095	22,158	140,261	0.1
50% want paper; 90-day usage with 7 day (or less) gap	2,698,064	N/A	50%	0.01095	14,772	132,875	0.1
75% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	75%	0.01095	31,345	149,448	0.1
50% want paper; 30-day usage with 7 day (or less) gap	3,816,731	N/A	50%	0.01095	20,897	139,000	0.1
75% want paper; 7-day usage	7,163,615	N/A	75%	0.01095	58,831	176,934	0.2
50% want paper; 7-day usage	7,163,615	N/A	50%	0.01095	39,221	157,324	0.2
75% want paper; All opioid users (1 year)	11,027,271	N/A	75%	0.01095	90,561	208,665	0.2
50% want paper; All opioid users (1 year)	11,027,271	N/A	50%	0.01095	60,374	178,477	0.2
75% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	75%	0.01095	132,501	250,604	0.3
50% want paper; any opioid use in last 2 years excluding cancer and hospice patients	16,134,063	N/A	50%	0.01095	88,334	206,437	0.2
75% want paper; All Part D enrollees	46,759,911	N/A	75%	0.01095	384,016	502,119	0.5
50% want paper; All Part D enrollees	46,759,911	N/A	50%	0.01095	256,011	374,114	0.4

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 ($)
§ 423.128 (Education on Addiction: Update systems)	RK	288	288	2	576	86.14	49,617	0
§ 423.128 (Education on Addiction: Create materials)	RK	288	288	2	576	119.12	68,486	0
Total		**228**	**556**	**2**	**1,152**	**Varies**	**118,103**	**0**

*RK (recordkeeping).

ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)

We are proposing to codify certain Part C (at § 422.62(b)(4) through (25)) and Part D (at § 423.38(c)(11) through (32)) 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 proposing to establish 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 do not believe the proposed changes will adversely impact individuals requesting enrollment in Medicare health or drug plans, the plans themselves, or their current enrollees. Similarly, we do not believe the proposed changes would have any impact on the Medicare Trust Fund.

Our proposal represents the codification of existing policy on SEPs for exceptional circumstances that has been specified in sub-regulatory guidance for quite some time, as well as the addition of the two aforementioned new SEPs for exceptional circumstances. MA organizations and Part D plan sponsors are currently assessing applicants' eligibility for election periods as part of existing enrollment processes; therefore, no additional burden is anticipated from this proposal. However, because a burden estimate for determining an applicant's eligibility for an election period has not previously been submitted to OMB, due to inadvertent oversight, we are seeking their approval under the aforementioned OMB control numbers.

The burden for all Part D parent organizations is estimated at 155,564 hours (1,867,519 beneficiary SEP elections * 0.0833 hr) at a cost of $11,051,267 (155,564 hr * $71.04/hr) or $217,203 per Part D parent organization ($11,051,267 /53 Part D parent organization).

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 ($)
§ 422.38 (SEP Part D: Filling out enrollment forms)	R	53	1,867,519	0	155,564	71.04	11,051,267	11,051,267

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

Summary of Changes

Subject (Regulatory Citation)	Number of Respondents	Number of Responses	Total Time (hr)	Total Cost in 1st Year ($)	Total Cost in Subsequent Years ($)
Non-Rule Changes Associated with DMPs (§ 423.153)	209	46,054	39,106	20,057,710	12,128,321
ICRs Regarding Mandatory Drug Management Programs (DMPs) (§ 423.153)	79	316	6,718	3,043	134
ICRs Regarding Beneficiaries with History of Opioid-Related Overdose Included in Drug Management Programs (DMPs) (§ 423.100)	288	45,975	27,183	13,141,885	10,084,628
ICRs Regarding Beneficiaries' Education on Opioid Risks and Alternative Treatments (§ 423.128)	228	556	1,152	118,103	0
ICRs Regarding Special Election Periods (SEPs) for Exceptional Conditions (§§ 422.62 and 423.38)	53	1,867,519	155,564	11,051,267	11,051,267
TOTAL	**857**	**1,960,420**	**229,723**	**44,372,008**	**33,264,350**

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.