Supporting Statement Part A
Part D Drug Management Program
CMS-10874, OMB 0938-1465

BACKGROUND

The Centers for Medicare & Medicaid Services (CMS) request approval of this new information collection regarding Medicare Prescription Drug Program (Part D) Drug Management Program (DMP) requirements. The DMP collection instruments and related burden are currently accounted for under CMS-10141 (OMB control number 0938-0964).

This 2024 iteration removes the DMP requirements/burden from CMS-10141 and moves it under its own collection of information request (CMS-10874, OMB 0938-1465) for improved clarity and usability for interested parties. Changes to the currently approved DMP requirements and burden are associated with our April 23, 2024 (89 FR 30448) final rule (CMS-4205-F, RIN 0938-AV24), "Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Plan Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, and Health Information Technology Standards and Implementation Specifications Final Rule."[1]

Section 1860D-4(c)(5)(A) of the Social Security Act (the Act) requires that Part D sponsors have a DMP for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), which CMS currently defines as opioids and benzodiazepines. Through the DMP, sponsors coordinate with CMS, prescribers, and pharmacies to identify and manage coverage of FADs for potential at-risk beneficiaries (PARBs) and at-risk beneficiaries (ARBs). Regulations at 42 CFR 423.153(f) implementing section 1860D-4(c)(5) of the Act established interventions for beneficiaries who may attempt to obtain prescription opioids from multiple prescribers and/or pharmacies, which may be unaware that others are prescribing or dispensing for the same patient. Such interventions include the ability to limit coverage of FADs when a sponsor determines that a beneficiary is at risk for prescription drug abuse or misuse.

Under current DMP policy, CMS reports to a Part D sponsor any beneficiaries of such sponsor who meet the clinical guidelines described at § 423.153(f)(16), which CMS refers to as the minimum Overutilization Management System (OMS) criteria. Sponsors must review all beneficiaries meeting the minimum OMS criteria. Sponsors may apply the supplemental OMS criteria to their Part D member populations to identify additional individuals at potential risk for prescription drug misuse or abuse who may benefit from the sponsor's DMP. See section 4 of the 2023 Part D DMP Guidance ("DMP guidance") for detailed information about the minimum and supplemental OMS criteria.[2] Unless the sponsor determines that a beneficiary is exempt from the DMP under the definition at § 423.100, or does not meet the OMS criteria based on plan information, the sponsor must conduct case management for beneficiaries determined to be potentially at risk. Under § 423.153(f)(2), DMP case management must include informing the beneficiary's prescribers of the beneficiary's potential risk for misuse or abuse of FADs and requesting information from the

[1] https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit
[2] https://www.cms.gov/files/zip/cy-2023-part-d-dmp-guidance-april-20-2023.zip

prescribers relevant to evaluating the beneficiary's risk. During a coverage year, a PARB or ARB might transfer to a plan under a different Part D sponsor. In such situations, the losing sponsor must provide case management information regarding the PARB or ARB to the receiving sponsor, and the gaining sponsor must provide case management for the PARB or ARB henceforth.

If a sponsor determines through case management that a beneficiary is an ARB, the sponsor may limit their access to FADs to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit, in accordance with the requirements at § 423.153(f)(3). Sponsors may apply such limitations only after providing an Initial Notice and Second Notice in writing to such a beneficiary. The Initial Notice must inform the beneficiary that they have been identified as a PARB and must include information outlined in § 423.153(f)(5)(ii). The Second Notice must inform the beneficiary that they have been identified as an ARB and of the limitations on the beneficiary's coverage of FADs, as specified in § 423.153(f)(6)(ii). In the event that, after sending an Initial Notice, a sponsor determines that a PARB is not an ARB, a Second Notice would not be sent; instead, an Alternate Second Notice would be sent. CMS codified a requirement at § 423.153(f)(7) to provide an Alternate Second Notice for the purpose of informing the beneficiary that they are not an ARB and that no limitation on their coverage of FADs will be implemented under the DMP.

Under § 423.153(f)(15)(ii) and the DMP guidance, a Part D sponsor must disclose data and information related to their DMP, including each PARB identified, each PARB and ARB that has transferred to the sponsor, and any limitations imposed to a beneficiary's coverage of FADs. Sponsors must disclose such required data manually, through OMS, and through the Medicare Advantage Prescription Drug (MARx) system.

In addition to the DMP requirements/burden being moved under this collection of information request, we are also moving the currently approved DMP collection instruments and are making minor revisions to account for changes to the definition of "exempted beneficiary" that was finalized in CMS-4205-F, as well as other revisions deemed necessary for program operation. See sections 12 and 15 of this Supporting Statement for details.

A. JUSTIFICATION

1. Need and Legal Basis

Section 1860D-4(c)(5)(A) of the Act requires that Part D sponsors have a DMP for beneficiaries at risk of abuse or misuse of FADs. The information in this collection is necessary for sponsor conformance with DMP requirements at § 423.153(f), including communicating with prescribers and pharmacies, informing beneficiaries that they have been identified as a PARB or ARB, and informing beneficiaries and CMS whether a beneficiary's access to FADs will be restricted to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit.

2. Information Users

Pursuant to Section 1860D-4(c)(5)(A) of the SSA, Part D sponsors will use the standardized and model documents to communicate with providers, enrollees, and other sponsors. Specifically, Part

D sponsors may use the Model Part D Drug Management Program Prescriber Inquiry Letter to inform providers that their patient's pattern of use or history of use of FADs is potentially unsafe and has prompted a case management review under the plan's DMP. Part D sponsors must use the standardized Initial Notice and Second Notice, or Alternate Second Notice, to inform enrollees, following identification by CMS's OMS and subsequent case management, whether the beneficiaries have been identified as being potentially at risk or at risk for abuse or misuse of FADs. Part D sponsors may use the Model Part D Drug Management Program Sponsor Information Transfer Memorandum to communicate to a gaining sponsor the enrollee's history of misuse or abuse of FADs.

3. Improved Information Technology

Where feasible the collection of information included in this Information Collection Request (ICR) involves the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. Written information from a Part D sponsor to an enrollee's provider does not require a standardized form and may be sent electronically or faxed. Similarly, information regarding a PARB 2 or ARB 2 as defined in the DMP guidance may be sent electronically or faxed by the losing sponsor to the gaining sponsor. It is anticipated that sponsors maintain notice templates within automated computer systems so the content is communicated reliably and a digital record of notices being sent is documented. 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. Lastly, Part D beneficiaries have the option to request electronic delivery of standardized notices.

4. Duplication of Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

Small businesses that choose to participate in the MA or Part D programs are subject to the same requirements as other businesses. The requirements do not impose any greater burden on small businesses than on large businesses.

6. Less Frequent Collection

Consistent with the statutory and regulatory requirements discussed in section 1, the estimated burden in this information collection request represents the least frequent basis necessary for Part D sponsors to comply with CMS regulations and effectively manage their DMP.

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

Federal Register

Serving as the 60-day notice, the proposed rule (CMS-4205-P, RIN 0938-AV24) published in the Federal Register on November 15, 2023 (88 FR 78476).[3] We received no comments related to this collection of information requirements and burden estimates. Our final rule published on April 23, 2024 (89 FR 30448).[4] As the revised collection of information instruments did not post for public review, we are correcting that oversight by using the standard non-rule PRA process which includes the publication of 60- and 30-day notices in the Federal Register. The 60-day notice published on May 6, 2024 (89 FR 37227). Comments must be received by July 5, 2024.

Outside Consultation

When developing the standardized DMP beneficiary notices, CMS engaged in focus group testing with beneficiaries.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

Part D sponsors are required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and any other applicable laws and regulations to protect beneficiary information. Data collected through the Medicare Advantage Prescription Drug System (MARx) System includes

[3] https://www.federalregister.gov/documents/2023/11/15/2023-24118/medicare-program-contract-year-2025-policy-and-technical-changes-to-the-medicare-advantage-program

[4] https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit

information about a beneficiary's entitlement to Medicare benefits and enrollment in Medicare Programs, prescription drug coverage and supplementary medical claims information. The system contains personal identifying information and other demographic information.

CMS issued a System of Record Notice (SORN) (February 14, 2018; 83 FR 6591) for the Medicare Advantage Prescription Drug System (MARx) System (SORN Number: 09–70–0588). A Privacy Impact Assessment is not required because personal identifiable information is not being collected electronically.

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. Collection of Information Requirements and Annual Burden Estimates

Wage Data

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/2023/may/oes_nat.htm). The following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Table 1. National Occupational Employment and Wage Estimates

BLS Occupation	Occupation	Mean Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Wage ($/hr)
Pharmacist	29-1051	64.81	64.81	129.62
Pharmacy Technician	29-2052	20.83	20.83	41.66
Physicians, All Other	29-1229	119.54	119.54	239.08

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Information Collection Requirements and Burden Estimates

One-Time Burden

Changes to the collection instruments are minimal, requiring only minor edits and no reformatting on the existing instruments. Because sponsors have been required to have DMPs since 2022, and many have had DMPs in place since 2019, sponsors will not need to create new systems or processes. The change in definition of exempted beneficiary will be a factor considered during case management, for which there is an estimated annual burden. Therefore, we estimate that there is no measurable one-time burden associated with this ICR.

Annual Burden

Under § 423.153(a), all Part D sponsors must have a DMP to address overutilization of FADs for beneficiaries in their prescription drug benefit plans. Based on 2023 data, there are 319 Part D parent organizations. The provisions codified at § 423.153(f)(2) require that Part D sponsors conduct case management of beneficiaries identified by the minimum OMS criteria through contact with their prescribers to determine if a beneficiary is at risk for abuse or misuse of FADs. Case management must include informing the beneficiary's prescriber(s) of the beneficiary's potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary. Under current CMS regulations at § 423.100, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP.

In 2022, the OMS identified 43,915 PARBs meeting the minimum criteria prior to applying exclusions and 30,411 after excluding exempted beneficiaries. Thus, 13,504 beneficiaries met the definition of exempted beneficiary. Amending the definition of "exempted beneficiary" at § 423.100 by replacing the reference to "active cancer-related pain" with "cancer-related pain," will result in 46 additional beneficiaries meeting the definition of exempted beneficiary, or 13,550 exempted beneficiaries total. This yields 30,365 beneficiaries requiring case management under the amended definition.

We estimate it takes an average of 5 hours for a sponsor to conduct case management for 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 $129.62/hr, 2 hours would be conducted by a pharmacy technician at $41.66/hr, and 1 hour would be conducted by a physician at $239.08/hr to work directly with prescribers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of $581.64 per PARB case managed ([2 hr x $129.62/hr] + [2 hr * $41.66/hr] + [1 hr * $239.08/hr]). Therefore, the case management team's average hourly wage is $116.33/hr ($581.64 / 5 hr). CMS data from 2022 estimates that annually 30,365 PARBs would be identified after exclusions based on minimum OMS criteria. In aggregate, we estimate annual burden for 30,365 beneficiaries annually subject to case management to be 151,825 hours at a cost of $17,661,802per year (30,365 beneficiaries* 5 hours * $116.33/hr for the case management team).

As a result of case management, a portion of PARBs may receive notice from a 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 OMS criteria receive an Initial Notice and either a Second Notice or an Alternate Second Notice.

We estimate the burden for sending notices will be reduced both by amending the definition of "exempted beneficiary," and by updating the estimate included in CMS-10141 of beneficiaries with a history of opioid-related overdose. Under Section 2006 of the SUPPORT Act, Congress required CMS to include Part D beneficiaries with a history of opioid-related overdose as PARBs under a Part D plan's DMP. Since then, through program experience, we have revised our estimate to reflect that 5 percent of all PARBs, including those with a history of opioid-related overdose would receive a DMP notice.

Using 2022 data, we estimate there will be 30,365 PARBs. This accounts for the 46 additional individuals who would meet the amended definition of "exempted beneficiary" finalized in CMS-4205-F. Considering this definition change, 2 fewer PARBs will receive notices (46 * 0.05) and there would be 4 fewer notices total. Approximately 1,518 (30,365 * 0.05) PARBs overall would receive an Initial Notice and Second Notice (or Alternate Second Notice) annually. We estimate it takes a pharmacy technician at $41.66/hr approximately 5 minutes (0.0833 hr) to send each notice and a total of 10 minutes (0.1667 hr) per beneficiary to send both notices. In aggregate, we estimate an annual burden of 253 hours (1,518 beneficiaries* 0.1667 hr) at a cost of $10,540 (253 hr * $41.66/hr) to be attributed to notice requirements.

The definition change will also reduce the burden of disclosure of DMP data to CMS based on the outcome of case management of PARBs. Using 2022 data, 46 additional individuals meeting the definition of exempted beneficiary results in 30,365 instead of 30,411 beneficiaries requiring DMP data disclosure. We estimate it takes sponsors on average 1 minute (0.0167 hr) at $41.66/hr for a pharmacy 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 507 hours (30,365 PARBs * 0.0167 hr) at a cost of $21,122 (507 hr * $41.66/hr).

Consistent with § 423.153(f)(15)(ii)(E), sponsors are required to transfer case management information upon the request of a new sponsor when a PARB or ARB switches plans. CMS provides a sample transfer memo that sponsors may use to transfer such information. We have observed through program experience that this number is de minimis and as a result have removed the burden associated with § 423.153(f)(15)(ii)(E) from this package.

Table 2. Burden Summary for DMP

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Annual Time (hr)	Labor Cost($/hr)	Total Annual Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	151,825	116.33	17,661,802
423.153(f)(5) – (8)	Send Notices (Annualized)	319	1,518	0.1667	253	41.66	10,540
423.153(f)(15)	Report to CMS (Annualized)	319	30,365	0.0167	507	41.66	21,122
Total		**319**	**62,248**	**Varies**	**152,585**	**Varies**	**17,693,464**

Information Collection Instruments and Instruction/Guidance Documents

The DMP collection instruments consist of the following. With regard to changes, see section 15 of this Supporting Statement and the attached Crosswalk for details.

Conduct Case Management

- Model Prescriber Inquiry Letter (Revised)
- Model Sponsor Information Transfer Memorandum (No Change)

Send Notices

- Initial Notice (Revised)
- Second Notice (Revised)
- Alternate Second Notice (No Change)
- Instructions for DMP Notices (Revised)

Report to CMS

- Medicare Advantage Prescription Drug (MARx) system (No Change)

13. Capital Costs

All Part D 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

The costs to the federal government associated with DMPs include ongoing program administration and oversight. We estimate a GS-13 (step 1) employee will spend approximately 416 hours annually (20 percent of assigned duties) on such administration and oversight. Using the 2024 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington locality,[5] the adjusted hourly wage is $113.04/hr, based on the hourly wage of $56.52/hr multiplied by a factor of 100 percent to account for fringe benefits and other indirect costs. The total annual cost to the federal government is $47,025($113.04/hr x 416 hr).

15. Changes to Collection of Information Requirements, Burden, and Collection of Information Instruments

This is a new information collection request, in which we include information collection instruments and related requirements/burden from CMS-10141 (OMB control number 0938-0964) along with changes associated with our April 23, 2024 (89 FR 30448) final rule (CMS-4205-F, RIN 0938-AV24).[6]

[5] www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2024/DCB_h.pdf

[6] https://www.federalregister.gov/documents/2024/04/23/2024-07105/medicare-program-changes-to-the-medicare-advantage-and-the-medicare-prescription-drug-benefit

The DMP requirements/burden and instruments that are currently approved by OMB under CMS-10141 (OMB 0938-0964) will be removed from that control number once they are approved under this new collection of information CMS-10874 (OMB 0938-1465). As mentioned, we are moving the DMP requirements/burden and instruments from CMS-10141 to CMS-10874 to improve clarity and usability for interested parties.

We have accounted for the reduction of burden for case management, sending notices, and data disclosure associated with the change in definition of "exempted beneficiary" finalized in CMS-4205-F, RIN 0938-AV24. We revised the DMP notices, letter, and memorandum to incorporate the change in definition of "exempted beneficiary" finalized in CMS-4205-F and to include non-substantive, technical revisions determined necessary through program operation and described in the crosswalk document submitted with this package. We have clarified in the Initial Notice and Second Notice the length of time for which a coverage limitation is applied. We have removed burden associated with transferring case management information when an ARB or PARB switches plans because we observed through program experience that this number is de minimis. We are not removing any burden associated with sponsors no longer sending a Retraction Notice for Exempted Beneficiaries – sponsors will instead send an Alternate Second Notice under changes finalized in CMS-4205-F – because the Retraction Notice was not accounted for in CMS-10141.

We have updated the mean hourly wage, fringe benefits, and adjusted hourly wage using current Bureau of Labor Statistics Occupational Title, Occupational Code and Mean Hourly Wage data. For accuracy, we updated the number of Part D sponsors, beneficiaries receiving case management and/or coverage restrictions under their plan's DMP, and beneficiaries who transfer plans while receiving case management and/or coverage restrictions under their plan's DMP.

Table 3, presents information from the current package, CMS-10141, with wages adjusted to 2023 wages.

Table 3: Current Estimate of Burden Updated to Reflect 2023 Wages

Regulatory Citation	**Subject**	**Number of respondents**	**Number of responses**	**Time per response ($/hr)**	**Total Annual Time (hr)**	**Labor Cost ($/hr)**	**Total Cost ($)**
423.153(f)(2)	Conduct Case Management (Annualized)	306	35,771	5	178,855	116.33	20,806,202
423.153(f)(5) (8)	Send Notices (Annualized)	306	7,911	0.1667	1,319	41.66	54,950
423.153(f)(15)	Report to CMS (Annualized)	306	35,771	0.0167	597	41.66	24,871
Total		**306**	**79,453**	**Varies**	**180,771**	**Varies**	**20,866,023**

Table 4 presents the estimated burden in this ICR, CMS-10874, which uses the currently approved burden from CMS-10141 as a baseline. The information in Table 4 aligns with the information in Table 2.

Table 4: Estimate of Burden in this ICR, CMS-10874

Regulatory Citation	Subject	Number of respondents	Number of responses	Time per response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	151,825	116.33	17,661,802
423.153(f)(5) - (8)	Send Notices (Annualized)	319	1,518	0.1667	253	41.66	10,540
423.153(f)(15)	Report to CMS (Annualized)	319	30,365	0.0167	507	41.66	21,122
Total		**319**	**62,248**	**Varies**	**152,585**	**Varies**	**17,693,464**

In aggregate, the changes associated with this ICR result in an annual estimated reduction of responses (17,208), reduction in cost ($3,172,559), and reduction in hours (28,186). The aggregate burden change (reduction) is presented in Table 5.

Table 5: Burden Changes

Regulatory Citation	Subject	Number of responses	Time per response (hr)	Total Time (hr)	Labor Cost ($/hr)	Total Cost ($)
423.153(f)(2)	Conduct Case Management (Annualized)	(5,406)	5	(27,030)	116.33	(3,144,400)
423.153(f)(5) – (8)	Send Notices (Annualized)	(6,393)	0.1667	(1,066)	41.66	(44,410)
423.153(f)(15)	Report to CMS (Annualized)	(5,406)	0.0167	(90)	41.66	(3,749)
Total		**Varies**	**Varies**	**(28,186)**	**Varies**	**(3,172,559)**

16. Publication and Tabulation Dates

Revisions to the notices will be announced through HPMS and published on cms.gov on unspecified dates. Results of this information collection will not be published for statistical use or analysis.

17. Expiration Date

The expiration date is displayed on the collection instruments.

18. Certification Statement

There are no exceptions to the certification statement.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no statistical methods, surveys, or questionnaires.