Supporting Statement, A
The Medicare Advantage and Prescription Drug Programs: Part C and Part D
Medicare Advantage Prescription Drug (MARx) System Updates for the Medicare Prescription Payment Plan Program
(CMS-10887; OMB 0938-New)

Background

The Centers for Medicare & Medicaid Services (CMS) requests the approval of new information collection for the Medicare Prescription Drug Program (Part D). We are proposing a new collection of beneficiary-level data elements specific to the Maximum Monthly Cap on Cost-Sharing Payments Program, which was established under Section 11202 of the Inflation Reduction Act of 2022, Public L. 117-169 (IRA). The official name of the program is the Medicare Prescription Payment Plan program.

Specifically, the IRA amended the Act by adding section 1860D–2(b)(2)(E) which, beginning January 1, 2025, establishes the Medicare Prescription Payment Plan program (hereinafter referred to as the "program"). Under this program, MA Organizations offering Part D coverage and Part D sponsors (collectively "Part D plans" or "Plans") are required to offer enrollees the option to pay their Part D cost sharing in monthly amounts spread out over the plan year based on the formulae described in section 1860D-2(b)(2)(E)(iv) of the Act.

To effectively monitor the program, Part D plans will be required to report data elements related to the program at the beneficiary, contract, and Plan Benefit Package (PBP)[1] levels beginning in Contract Year (CY) 2025. In this information collection package, we address the proposal to require Part D plans to submit beneficiary-level data elements into the MARx system via a program-specific transaction (separate from the enrollment file). In accordance with the Plan Communication User Guide (PCUG), plans may submit multiple transaction files during any CMS business day, Monday through Friday. Plan transactions are processed as received; there is no minimum or maximum limit to the number of files that Plans may submit in a day. In general, transaction and processing occur throughout the Current Calendar Month (CCM). For CY 2025, CMS will not require independent data validation for this new MARx reporting requirement.

Part D sponsors would submit the following beneficiary-level data elements into MARx via Connect: Direct or TIBCO MFT Internet Server:

1) Contract Number
2) PBP Number
3) Medicare Beneficiary Identifier (MBI) Number
4) Beneficiary first name
5) Beneficiary last name
6) Beneficiary date of birth (DOB)
7) Date of effectuation into the Medicare Prescription Payment Plan
8) Date of election termination from the Medicare Prescription Payment Plan
9) Election termination reason code (voluntary versus involuntary).

[1] Please refer to OMB Control No. 0938-0992 for additional information on contract-level and PBP-level reporting requirements, to be made available here: https://hpms.cms.gov/app/ng/home/.

A. JUSTIFICATION

1. Need and Legal Basis

Need
Our fundamental goal is to have the least burdensome data submission requirements necessary to acquire the data needed for accurate Medicare Prescription Payment Plan program oversight. CMS believes that collecting beneficiary-level data through MARx is the most effective way for us to oversee implementation of this program. Beneficiary-level data will enable CMS to better understand participation patterns across different populations, address enrollee concerns related to the program in near real-time and inform CMS of changes to potential guidance and program requirements in the future. We limit our data collection to those critical data elements that are necessary for understanding which enrollees are participating in the program, how many have chosen to opt-out of the program after joining, and how many have been terminated from the program by their Part D sponsor, all of which are necessary for ensuring program integrity and oversight.

Legal Basis
42 CFR § 423.514(a) requires each Part D sponsor to have an effective procedure to develop, compile, evaluate, and report to CMS, its Part D enrollees, and the public, at the times and in the manner that CMS requires, statistics indicating the following:

1) The cost of its operations.
2) The patterns of utilization of its services.
3) The availability, accessibility, and acceptability of its services.
4) Information demonstrating that the Part D sponsor has a fiscally sound operation.
5) Pharmacy performance measures.
6) Other matters that CMS may require.

2. Information Users

The information users are Part D sponsors, specifically Part D plans. All Part D plans will be required to submit this data to CMS for each enrollee that participates in the program. Additionally, Part D plans must include any changes to an enrollee's status in the program (enrollee is terminated from the program to failure to pay, enrollee voluntarily ends their participation in the program), as discussed in more detail in Section 12. CMS information users will leverage the beneficiary-level MARx program to ensure compliance with program requirements, to understand participation patterns across different populations, address enrollee concerns related to the program in near real-time, and to inform CMS of potential changes to guidance and program requirements in the future.

3. Use of Information Technology

The Medicare Advantage Prescription Drug System (MARx) stores Medicare Advantage Organization (MAO), Part C and Part D Sponsor, and Part D enrollment, payment, and premium information and calculates monthly Part C/D payments and adjustments for each Plan. MAOs and Part D sponsors can submit batch data files, view information on the User Interface (UI), and

download reports via MARx. In addition, the MARx System of Record Notice (SORN) describes the purpose of the MARx system as follows: "The primary purpose of the SOR is to maintain a master file of Medicare Advantage (MA) and Medicare Advantage Prescription Drug (MA–PD) plan members for accounting and payment control; expedite the exchange of data with MA and MA–PD; control the posting of pro-rata amounts to the Part B deductible of currently enrolled MA members; and track participation of the prescription drug benefits provided under prescription drug plans (PDPs) and Medicare employer plans. (70 FR 60530)."

For Medicare Prescription Payment Plan beneficiary-level data submissions, CMS proposes to process these transactions using the same process currently in place for enrollment file submissions in MARx. Please note that unlike enrollment file submissions, beneficiary-level data submissions specific to the Medicare Prescription Payment Plan will not have any impact on plan payments.

In general, transaction and processing for the Medicare Prescription Payment Plan beneficiary-level data submissions will occur throughout the CCM. CMS proposes the following steps to process transactions from a Plan:

1. Plans submit transaction files using the selected data exchange method (TIBCO or Connect:Direct)
2. MARx processes the submitted transactions, resulting in actions that reflect beneficiaries' status in the Medicare Prescription Payment Plan
3. The Plan receives MARx-accepted transactions in the *Daily Transaction Reply Report* (DTRR). These records contain a Transaction Reply Code (TRC), which describes the CMS response.
4. An unaccepted transaction results in either a rejected or failed status.
    a. A ***rejection*** results when incoming data is of the correct type but is not successfully processed due to some inconsistency that violates an enrollment validation check or rule. For example, if the contract number does not identify a valid contract for the submitter, MARx rejects the transaction. Rejected transactions are reported on the DTRR and transmitted to the Plan.
    b. A ***failure*** results when incoming data is inconsistent with the database rules. A transaction fails during processing when it contains an error that is too severe to attempt to process and store the data in the system. The transaction is written to the *Batch Completion Status Summary* (BCSS) report and transmitted to the Plan.

All data (100%) will be collected by CMS electronically.

See section 12 of this Supporting Statement under Collection of Medicare Prescription Payment Plan Beneficiary-Level Data for a description of the dataflow.

4. Duplication of Efforts

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

5. Small Businesses

Small businesses are subject to the same requirements as other businesses as specified in Section 1860D–2(b)(2)(E)(v)(III) of the Act. The requirements do not impose any greater burden on small businesses than on large businesses.

6. Collection Frequency

As discussed above, CMS proposes to require Plans to submit beneficiary-level Medicare Prescription Payment Plan data to CMS using the same process as the enrollment file submissions. Plans will be required to submit data on an ongoing basis as beneficiaries are enrolled or disenrolled from the Medicare Prescription Payment Plan program. As noted above, plans may submit multiple transaction files during any CMS business day, Monday through Friday. Plan transactions are processed as received; there is no minimum or maximum limit to the number of files that Plans may submit in a day.

If information collection occurs less frequently than proposed, or there is no information collection at all, CMS will have a limited ability to understand the impact of the program on Part D enrollees and correct issues that require action by CMS. This frequency of information collection ensures oversight and integrity of the program and helps inform any future changes to the program.

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 agency more often than changes occur to participation in the program by a plan's enrollees, as described above;
- 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/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register (89 FR 5239) on January 26, 2024. CMS received a total of 13 comments.

- CMS received 12 comments from health plans, pharmacy benefit managers, and health IT companies requesting clarification on topics including the technical specifications for data submissions, the definitions of required data elements, and the implications of plan switching for Medicare Prescription Payment Plan program participation. CMS has made minor technical edits to the Supporting Statement and Appendix A in response to comments.

- CMS received 1 out of scope comment from a beneficiary.

The 30-day notice published in the Federal Register (89 FR) on TBD.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The data are protected and kept confidential under SORN "Medicare Advantage Prescription Drug (MARx) System, No. 09–70–4001," (originally published October 18, 2005; 70 FR 60530).

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 Estimates

Active Collection of Information and Associated Burden Estimates

The burden placed on Part D sponsors (contracts) associated with submitted beneficiary-level Medicare Prescription Payment Plan program data is predicated upon the following factors: (a) the amount of data that must be submitted; (b) the number of plans submitting data; and (c) the time required to complete the data processing and transmission transactions.

(a) Beneficiary-Level Program Data Submission: The amount of data that must be submitted is a function of the number of enrollees likely to enroll in the program and the number of enrollees voluntarily or involuntarily terminated from the program. Based on internal analyses, CMS estimates that between 435,000 and 3,200,000 enrollees will participate in

the Medicare Prescription Payment Plan. We assume that a plan will submit on average 3 records related to beneficiary participation in the program (enrollment, disenrollment, and then potentially one re-enrollment) per year. Assuming 3,200,000 enrollees participate and an average of 3 submissions per beneficiary per year, the projected average number of beneficiary-level program data submissions per year is 9,600,000.

(b) Number of Part D Contracts (Respondents): The average number of Part D contracts per year is 856 (based on 2019, 2020, and 2021 data).

(c) Time Required to Process Data: The third factor that contributes to the burden estimate for submitting beneficiary-level program data is the time and effort necessary to complete data transaction activities. Since our proposed process will follow the existing submission and transaction process as the enrollment file submissions, but using a different record format, we estimate this will require an average processing time of 1 hour per 250,000.

All three factors are reflected in Table 1 and illustrate the relationship between these results and the burden estimate.

Table 1: Annual Costs to Respondents Estimate for Active Collection of Information

FIELD	DESCRIPTION	DATA	NOTES
A	NUMBER OF RESPONDENTS	856	856 is the annual average number of Part D contracts from 2020, 2021, and 2022
B	NUMBER OF MEDICARE BENEFICIARIES ENROLLED IN PART D PER YEAR	50,028,700	Average number of Medicare beneficiaries enrolled in Part D
D	PROJECTED NUMBER OF PROGRAM PARTICIPANTS PER YEAR	3,200,000	
E	PROJECTED FREQUENCY OF RESPONSE	3 per beneficiary per year	Each file will include a record of every enrollee in the M3P program and their status
F	NUMBER OF TRANSACTIONS PER HOUR	250,000	Estimated average processing volume per hour
G	TOTAL ANNUAL TRANSACTION HOURS	38.4	(D) multiplied by (E) divided by (F)
H	AVERAGE ELECTRONIC COST PER HOUR	$17.75	Based on $17.75 per hour, the risk adjustment estimated average annual electronic processing cost per hour
I	COST OF ANNUAL TRANSACTION HOURS	$681.60	(H) multiplied by (G)
J	ANNUAL TRANSACTION HOURS/RESPONDENT	0.04	Number of hours needed to process one contract's MPPP beneficiary-level data (G) divided by (A)
K	AVERAGE COST PER PART D BENEFICIARY	.0002	(I) divided by (D)
L	ANNUAL TOTAL AVERAGE COST TO RESPONDENTS	$0.79	(J) multiplied by (H)

One-Time Burden Estimates Resulting from Addition of New MARx File and Addition of Program-Specific Fields

The addition of beneficiary-level data for program participants will require the development of a new record that is to be submitted to MARx. The burden associated with this one-time requirement to add to the existing MARx monthly calendar submission process is related to updating the systems and files to accommodate such changes.

(a) Number of Part D Respondents: The average number of Part D Contracts offering a Part D plan per year (Row (B)) is 856 (based on 2019 – 2021 internal CMS data).

(b) Total Number of Responses: The total number of responses equals the total number of respondents, because for the one-time burden estimates, each entity will need to make system changes.

(c) Labor Costs and Time Required: The hourly wage rate for this labor category was taken from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). The hourly wage is multiplied by a factor of 2 to account for fringe benefits and overhead (as shown in Table 2).

Table 2: Adjusted Hourly Wages Used in Burden Estimates

Occupation Title	Occupational Code	Median Hourly Wage ($/hr.)	Fringe Benefits and Overhead ($/hr.)	Adjusted Hourly Wage ($/hr.)
Software Developers	15-1252	61.18	61.18	122.36
Software Quality Assurance Analysts and Testers	15-1253	47.89	47.89	95.78
Database Administrators	15-1242	48.03	48.03	96.06
Computer Systems Analysts	15-1211	49.15	49.15	98.3

In calculating the burden of this proposal, we must consider the following:

- On average, for each of the 856 Part D Contracts, 2 software developers working at $122.36/hr spend 20 hours performing system maintenance with an aggregate per contract dollar burden of $ 4,189,606.

    - Based on internal CMS data, there are 856 Part D Contracts. The burden of update requires that 2 software developers will each spend 20 hours performing necessary redesigns. Therefore, the aggregate burden across all 856 Part D contracts is 34,240 hours (2 software developers x 20 hours a developer x 856 Part D Contracts).

    - Thus, the total cost is $ 4,189,606(34,240 hours x $122.36 wage/hr)

- On average, for each of the 856 Part D Contracts, a Software Quality Assurance Analyst and Tester working at $95.78/hr spends 10 hours performing quality assurance and testing with an aggregate per contract dollar burden of $819,877(1 Software Quality Assurance Analyst and Tester x 10 hours x 856 Part D Contracts x $95.78 wage/hr).

- On average, for each of the 856 Part D Contracts, 1 Database Administrator (DBA) working at $96.06/hr spends 10 hours performing system maintenance with an aggregate

per contract dollar burden of $ 822,274 (1 DBA x 10 hours a DBA x 856 Part D Contracts x $96.06 wage/hr).

- On average, for each of the 856 Part D Contracts, 1 Computer Systems Analyst working at $98.30/hr spends 10 hours performing system maintenance with an aggregate per contract dollar burden of $841,448 (1 Computer Systems Analyst x 10 hours x 856 Part D Contracts x $98.30 wage/hr).

Total Costs: The total cost for all 856 Part D Contracts is $ 6,673,205 ($4,189,606 + $ 819,877 + 822,274 + $ 841,448) (see Table 3 below).

Table 3: One-Time Burden Estimates – Addition of New MARx File and Addition of Program-Specific Fields

Estimated Number of Respondents	Burden per Response (hours)	Total Annual Burden (hours)/contract	Wages / hr ($)	Total Estimated Labor Cost ($)
856	40	34,240	122.36	4,189,606
856	10	8,560	95.78	819,877
856	10	8,560	96.06	822,274
856	10	8,560	98.3	841,448
Total	**70**	**59,920**		**6,673,205**

Information Collection/Reporting Instruments and Instruction/Guidance Documents

- HPMS guidance announcing software changes to the MARx system.
- Appendix A provides an example technical layout for the submission of the data elements described in this ICR.
- Revisions to the user guide previously entitled, "Plan Communication User Guide for Medicare Advantage Prescription Drug Plans, October 31, 2023, Version 17.3." (Available at: https://www.cms.gov/files/document/plan-communications-user-guide-october-31-2023-v173.pdf).

Submission Requirements

The IRA requires all Part D sponsors to offer enrollees the option to pay their Part D cost sharing in monthly amounts spread out over the plan year based on the formula described in section 1860D-2(b)(2)(E)(iv) of the Act.

The requirements for submitting the data provide that the data will be used to monitor and oversee implementation of the Medicare Prescription Payment Plan program. We propose to require that plans submit an updated Medicare Prescription Payment Plan file that includes all enrollees that have elected to participate in the program or were terminated from the program (voluntarily or involuntarily). The Medicare Prescription Payment Plan file is a summary record that documents all enrollee's participating in the program for each contract-PBP.

Please refer to Appendix A for an example of a potential MARx Medicare Prescription Payment Plan file layout.

The following details the Medicare Prescription Payment Plan beneficiary-level program dataflow:

- The plan submits all Medicare Prescription Plan Payment transactions to CMS via MARx in accordance with the forthcoming Year 2025 MARx Monthly Calendar (see the Year 2024 MARx Monthly Calendar here as a reference: https://www.cms.gov/files/document/year-2024-marx-monthly-calendar-color.pdf)
    - Plans may submit multiple transaction files during any CMS business day, Monday through Friday. Plan transactions are processed as received; there is no minimum or maximum limit to the number of files that Plans may submit in a day.
    - All Plan-submitted files should comply with the record formats and field definitions as described for each file type. Plans should send files in a flat file structure that conform to the Dataset Naming Conventions unique to each file type.
    - CMS recognizes Plan submitted files by the information supplied in the Header and Trailer Records. Header Record information is critical as CMS uses it to track, control, formulate, and route files and transactions through the CMS systems and is used to send response files back to the Plans.
    - In general, transaction and processing occur throughout the CCM. Transactions processed on or before the Plan Data Cut-Off date will be included in the prospective payment to the Plan.
    - After the Cut-Off date, the MARx month-end process performs the payment calculation of beneficiary-level payments to Plan-level payments. While CMS is reviewing monthly payments for approval, Plan transaction processing resumes for the next month. Once CMS approves the monthly prospective payments, reports are distributed to the Plans.
- MARx processes the submitted transactions.
- The Plan receives accepted transactions in the *Daily Transaction Reply Report* (DTRR). These records contain a Transaction Reply Code (TRC), which describes CMS response.
- An unaccepted transaction results in either a rejected or failed status.
    - A ***rejection*** results when incoming data is of the correct type but is not successfully processed due to some inconsistency that violates an enrollment validation check or rule. For example, if the contract number does not identify a valid contract for the submitter, MARx rejects the transaction. Rejected transactions are reported on the DTRR and transmitted to the Plan.
    - A ***failure*** results when incoming data is inconsistent with the database rules. A transaction fails during processing when it contains an error that is too severe to attempt to process and store the data in the system. The transaction is written to the *Batch Completion Status Summary* (BCSS) and transmitted to the Plan.

13. Capital Costs

Any administrative and/or capital costs incurred will be recouped through the bidding process and secured through the reinsurance and/or risk corridors processes. The average number of Part

D contracts per year is 856 (based on 2019, 2020, and 2021 data). These entities have sufficient capital assets in place to address reporting drug data. MA-PD plans also have sufficient capital assets in place to address drug data reporting.

14. Costs to Federal Government

The costs to the federal government associated with the Medicare Prescription Payment Plan MARx beneficiary-level data submissions include one-time costs to update the MARx system to accept new reports and data fields, as well as annual costs review the data submissions and generate transactions reports.

To generate the salary estimates in the tables below, we used the 2023 General Schedule (GS) Locality Pay Tables published by the Office of Personnel Management (OPM) for the Washington-Baltimore-Arlington locality. [2] We adjusted the hourly wage of $53.67/hr for a GS-13 (step 1) by a factor of 100% to account for fringe benefits, for an adjusted hourly wage of $107.34/hr.

One-Time Costs
Implementing the Medicare Prescription Payment Plan MARx beneficiary-level data submissions involves one-time costs to update MARx to accommodate the new report and data fields (see Appendix A). These efforts will be undertaken by CMS employees and contractors.

Based on information provided by CMS contractors, the cost of the MARx updates is estimated to be $17,367. This task will be overseen by a CMS employee. We estimate that one GS-13 employee will spend approximately 50 hours to oversee this task, at an adjusted hourly wage of $107.34/hr, for a total cost of $5,367. These estimates are reflected in Table 4. Therefore, annualized over the 3-year approval period, the one-time costs are $5,789 per year ($17,367 / 3).

Table 4: One-time Cost to Government to Develop MARx MPPP File Format and Reporting for the MARx Update

Cost Category	**Cost**
Develop MARx MPPP File Format and Reporting for the MARx Updates	
GS-13 (step 1): $107.34/hr x [50] hrs	$5,367
Contractor Support $120/hr x [100] hrs	$12,000
Total One-Time Cost to Federal Government	**$17,367**
Total Annualized One-Time Cost to Federal Government	**$5,789**

Annual Costs
We estimate annual costs to the government for collecting beneficiary-level Medicare Prescription Payment Plan information and distributing reports to Part D Sponsors, including invoices from MARx contractors. These tasks will also be overseen by a CMS employee. We estimate that one GS-13 employee will spend approximately 480 hours to oversee these tasks, at an adjusted hourly wage of $107.34/hr, for a total cost of $51,523 for each task. We also estimate that one contractor will spend approximately 960 hours, at an hourly wage of $120/hr, for a total cost of $115,200. Combined the total annual cost is $166,723. These estimates are reflected in Table 5.

[2] https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2023/DCB_h.pdf

Table 5: Annual Cost to Government for MARx MPPP Data Submissions – Processing and Reporting (Operations and Maintenance)

Category	**Cost**
MARx MPPP Data Submissions – Processing and Reporting (Operations and Maintenance)	
GS-13 (step 1): $107.34/hr x [480] hrs	$51,523
Contractor Support $120/hr x [960] hrs	$115,200
Total Annual Cost to Federal Government	**$166,723**

15. Changes to Requirements and Burden

This is a new collection.

16. Publication/Tabulation Dates

The purpose of this data submission request is to support oversight and program integrity for Part D enrollees who participate in the Medicare Prescription Payment Plan program. There are no publication and tabulation dates.

17. Expiration Date

The expiration date is displayed within the PRA Disclosure Statement and can be found on Reginfo.gov under OMB Control No. XX (available at XX). Both the expiration date and PRA Disclosure Statement are placed in Appendix A.

18. Certification Statement

CMS has no exceptions to Item 19, "Certification for Paperwork Reduction Act Submissions" of OMB Form 83-I.

B. Collection of Information Employing Statistical Methods

Requirements for this data collection do not employ statistical methods.