

Supporting Statement (Part A)
Collection of Prescription Drug Event Data
From Contracted Part D Providers for Payment
(CMS-10174, OMB 0938-0982)

The requirements referenced in this Supporting Statement assist with the implementation of the provisions of the Social Security Act to effectuate and monitor the Medicare Prescription Drug Benefit and support the continued administration of the program. The approved Information Collection Request (ICR) is being revised to update burden estimates based on changes to the prescription drug event (PDE) record layout, specifically reflecting updates to existing fields described under the previously approved ICR.

We are also revising the package to update burden estimates based on the number of contracts as well as the growth of Medicare beneficiaries enrolled in Part D.

Background

In December 2003, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108-173), referred to as the Medicare Modernization Act (MMA). The Medicare Prescription Drug Benefit program (Part D) was established by section 101 of the MMA and is codified in sections 1860D-1 through 1860D-41 of the Social Security Act (hereinafter, “the Act”). Effective January 1, 2006, the Part D program established an optional prescription drug benefit for individuals who are entitled to Medicare Part A and/or enrolled in Part B. In general, coverage under the prescription drug benefit is provided predominantly through private at-risk Prescription Drug Plans (PDPs) that offer drug-only coverage, Medicare Advantage (MA) plans that offer integrated prescription drug and health care coverage (MA-PD plans), or through Cost Plans that offer prescription drug benefits.

The Patient Protection and Affordable Care Act, as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010, establishes the Coverage Gap Discount Program (CGDP) by adding sections 1860D-14A and 1860D-43 of the Act. Effective January 1, 2011, the CGDP provides manufacturer discounts to applicable Medicare beneficiaries receiving covered Part D drugs during the coverage gap phase of the benefit.

Section 9008 of the Patient Protection and Affordable Care Act (ACA; P.L. 111-148), as amended by section 1404 of the Health Care and Education Reconciliation Act of 2010 (HCERA; P.L. 111-152), imposes an aggregate annual fee on certain manufacturers of branded prescription drugs (please refer to section 9008(e)(2) of the ACA for a definition of branded prescription drugs). CMS is required to provide dollar amounts of sales of branded prescription drugs under the Medicare Part D program on a yearly basis to the Secretary of the Treasury in order to determine the fee amount to be paid by each manufacturer.

The Inflation Reduction Act (IRA), signed into law on August 16, 2022 (P.L. 117-169), makes a number of changes to the Part D program. It eliminates the deductible for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) and eliminates coinsurance or other cost sharing for these vaccines beginning January 1, 2023. § 1860D-2(b)(8) of the Act. It also eliminates the deductible for covered Part D insulin products and limits the beneficiary cost sharing for these insulin products beginning January 1, 2023. § 1860D-2(b)(9)

of the Act. For 2023 only, Medicare pays Part D sponsors a temporary retrospective subsidy (Inflation Reduction Act Subsidy Amount, or IRASA) for the reduction in cost sharing and deductible for insulins and ACIP-recommended adult vaccine, which equals the difference between the beneficiary cost sharing for the ACIP-recommended adult vaccine or covered insulin product under a Part D plan's 2023 benefit design (submitted by sponsors to CMS prior to the passage of the IRA) and the applicable statutory maximum cost sharing limit created by the IRA. § 1860D-15(h) of the Act.

The IRA provides for lower prices for certain high-priced single source drugs through a drug price negotiation process established by the Secretary, whereby a maximum fair price (MFP) is set for negotiation-eligible drugs beginning January 1, 2026. Part E of Title XI of the Act. It also requires manufacturers of Part D rebatable drugs to pay a rebate to Medicare if the drug's price during a 12-month period starting October 1, 2022, exceeds its inflation-adjusted benchmark price. The calculation excludes drug units discounted under section 340B of the Public Health Service Act. § 1860D-14B of the Act.

Finally, the IRA redesigns the Part D benefit by eliminating the cost sharing in the catastrophic phase in 2024; capping annual out-of-pocket costs for prescription drugs under Part D at \$2,000 for 2025 (updated each year by API); reducing the government reinsurance in the catastrophic phase of Part D coverage for applicable drugs from 80 percent to 20 percent and for non-applicable drugs from 80 percent to 40 percent beginning in 2025; eliminating the coverage gap phase and coverage gap discount program, and replacing it with a Manufacturer Discount Program (MDP) that requires manufacturers to provide a 10 percent discount in the initial phase and a 20 percent discount in the catastrophic phase on applicable drugs beginning in 2025; creating a new Selected Drug Subsidy Program beginning in 2026, under which Medicare covers the portion the manufacturer would otherwise pay under the MDP in the initial coverage phase of the benefit for the years in which a MFP applies for the drug; and requiring Part D sponsors to provide beneficiaries with the option to pay out-of-pocket costs under the plan in monthly amounts that are spread out throughout the year (Medicare Prescription Payment Plan). §§ 1860D-2(b), 1860D-15(b), 1860D-14A, 1860D-14C, 1860D-14D of the Act.

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 Part D payment and appropriate program oversight. We believe that claims data provide the most reliable approach to ensuring that payment calculations are accurate. Without claims-level data, we cannot verify the accuracy of payments related to reinsurance, risk corridors, low-income subsidies, CGDP reconciliation, MDP reconciliation, IRASA, and Selected Drug Subsidy. Additionally, we are unable to confirm the correctness of payments to fallback plans, should any exist for a given contract year.

This claims-level information is reported by Part D sponsors to CMS on the PDE record. We limit our data collection to only those critical data elements necessary for accurate payment-related calculations, along with other elements required for validation of the PDE record, quality monitoring, and program integrity and oversight.

We believe that, in order to fulfill the statutory requirements of the Act, the following PDE data categories are needed. Note that the examples of the fields in a given category are examples only and are not intended to be all inclusive or limit CMS' ability to add or remove fields in the future.

- Entity information (for example, Submitter ID, Contract No., and PBP ID)
- Beneficiary information (for example, Medicare Beneficiary Identifier (MBI) and Cardholder ID)
- Event Identification Information (for example, Date of Service and Claim Control Number)
- Drug and Quantity Identification Information (for example, Product Service ID and Compound Code)
- Cost Information (for example, Ingredient Cost and Sales Tax)
- Payment Breakout Information (for example, TrOOP Accumulator, Patient Pay and LICS)
- Prescriber information (for example, Prescriber national Provider Identifier (NPI) and DAW/Product Selection Code)
- Service Provider information (for example Pharmacy NPI and Pharmacy Service Type)
- Benefit Design information (for example, Benefit Phase, Tier, and Formulary Code)

We require this data on 100 percent of prescription drug claims or events for appropriate payment calculations, program auditing, administration of the manufacturer discount programs (CGDP and MDP), provision of the annual report to the Secretary of the Treasury consistent with section 9008 of the ACA, assessment and improvement of quality of care, administration of the drug price negotiation process, determination of the MFP for negotiation-eligible drugs, and administration of the Part D inflationary rebate process.

In addition, we generally use the PDE data submissions from Part D sponsors to fulfill our statutory obligations under the Social Security Act. This includes the use of PDE data to fulfill obligations or operationalize any future legislative changes to the Social Security Act that impact the Part D program.

Legal Basis

The following sections of the Act provide the statutory authority for the collection of data for the prescription drug benefit program:

- Payments – sections 1860D-11(g)(5), 1860D-14, 1860D-15, 1860D-22, and 1860D-14D.
- Data submission – sections 1860D-12(b)(3)(D), 1860D-15(c)(1)(C), 1860D-15(c)(2)(C), 1860D-15(d)(2), 1860D-15(f), 1860D-14A(c)(1)(C), and 1860D-14C(c)(3).
- Medicare Prescription Payment Plan – section 1860D-2(b)(2)(E).
- Manufacturer Inflationary rebates – section 1860D-14B.
- Drug Price Negotiation Program – Part E of Title XI.

The Voluntary Medicare Prescription Drug Benefit Applicable regulations are codified at 42 CFR Part 423. The Medicare Advantage (MA) Program regulations are codified at 42 CFR Part 422 (note there are a number of references to the MA program in the Medicare Part D statutory provisions).

Regulations applicable to the prescription drug data submission are as follows:

42 CFR 423.301 implements section 1860D-15 of the Act and the deductible and cost sharing provisions are addressed in section 1860D-14(a) of the Act. This section sets forth rules for the calculation and payment of our direct and reinsurance subsidies for Part D plans; the application of risk corridors and risk sharing adjustments to payments; and retroactive adjustments and reconciliations to actual enrollment and interim payments.

42 CFR 423.322, 423.329, and 423.343 implement sections 1860D-15(c)(1)(C), 1860D-15(c)(2)(C), 1860D-15(d)(2), 1860D-15(f), and 1860D-14D of the Act. These provisions set forth the requirement that payments to a Part D sponsor are conditioned upon provision of information necessary to CMS to carry out payment.

42 CFR 423.325 sets forth the rules for timely PDE submissions.

42 CFR 423.771, 423.772, 423.780, 423.782, and 423.800 implement section 1860D-14 of the Act. This section sets forth rules for premiums and cost sharing subsidies for low-income beneficiaries.

42 CFR 423.875 implements section 1860D-11(g) of the Act, and sets forth, but not limited to, the amount payable for a fallback prescription drug plan in accordance with § 423.871(e).

Subpart W of part 423 implements sections 1860D-14A and 1860D-43 of the Act. 42 CFR 423.2325 requires Part D sponsors to provide CMS with appropriate data on the applicable discounts provided by the Part D sponsors in a manner specified by CMS.

Subpart AA of part 423 implements section 1860D-14C of the Act and provisions included in section 1860D-43 of the Act. 42 CFR 423.2736 requires that the Part D sponsor report the applicable discounts made available to their enrollees under the Manufacturer Discount Program on the PDE data associated with such discounts.

42 CFR 422.310 sets forth rules for submitting data that can be linked at the individual level to Part A and Part B data.

42 CFR 423.505(f)(3) implements section 1860D-12(b)(3)(D) of the Act to allow the Secretary to collect the same claims information collected under the authority of section 1860D-15 of the Act for purposes deemed necessary and appropriate by the Secretary, including reporting to the Congress and the public, conducting evaluations of the overall Medicare program, making legislative proposals to Congress, and conducting demonstration projects.

2. Information Users

The information users will be pharmacy benefit managers (PBMs), third party administrators and pharmacies, PDPs, MA-PDs, Fallbacks, and other plans that offer coverage of outpatient prescription drugs under the Medicare Part D benefit to Medicare beneficiaries. The statutorily required data is used primarily for payment and is used for claim validation as well as for other

legislated functions such as quality monitoring, program integrity and oversight. In addition, the PDE data are used to support operations and program development.

Annually, CMS publishes a Public Use File (PUF) that summarizes the annual low-income reconciliation amount, the reinsurance reconciliation amount, the risk corridor amount, and the total Part D payment reconciliation amount (which is a sum of the 3 previously stated amounts). The PDE data are one of the inputs used to determine these reconciliation amounts.

CMS has used PDE data to create summarized dashboards and tools, including the Medicare Part D Drug Spending Dashboard & Data, the Part D Manufacturer Rebate Summary Report, and the Medicare Part D Opioid Prescribing Mapping Tool. The data are also used in the Medicare Trustees Report. Due to the market sensitive nature of PDE data, external uses of the data are subject to significant limitations. However, CMS does analyze the data on a regular basis to determine drug cost and utilization patterns in order to inform programmatic changes and to develop informed policy in the Part D program.

CMS information users leverage data reported under sections 1860D-15(c)(1)(C) and (d)(2) to implement the Medicare Drug Price Negotiation Program and calculate inflation rebates. We also use the data reported to fulfill our statutory obligations under the Social Security Act, which includes the use of PDE data to fulfill obligations or operationalize any future legislative changes to the Social Security Act that impact the Part D program.

3. Use of Information Technology

All data (100%) is collected by CMS electronically. Drug event data can be submitted via the Medicare Data Communications Network (MDCN) utilizing Internet Protocol (IP) and Secure File Transfer protocol (SFTP) or Systems Network Architecture (SNA) and Connect:Direct, or through the CMS TIBCO mail boxing system. Production PDE data are submitted into the PDFS and DDPS. When data are submitted, each system applies various edit checks to the data and issues response reports to submitters describing data that was accepted, rejected, and any errors that were or may be present in the data, so that plans can manage, correct and resubmit their data as necessary.

The Drug Data Processing System (DDPS) is the information system that collects, validates and stores PDE data received from PDPs, MA-PDs, Fallback and other plans offering coverage of outpatient prescription drugs under the Medicare Part D benefit. PDE data enter the DDPS through the Prescription Drug Front-End System (PDFS).

Once the plan sponsors or their PBMs or other third-party administrators have received drug claims from pharmacies and completed their “in-cycle” events, PDFS receives the PDE data at least monthly, and in the case of Selected Drugs, at least once every 7 calendar days consistent with 42 CFR 423.325(b). Plan sponsors or their third-party submitters must submit PDE data electronically. The PDFS performs file format and face validity checks. PDFS edits are available at <https://csscooperations.com/cssc/admin/cssc/tools/pdfs>.

Once the file has passed the front-end checks, it moves through the DDPS where detail-level (PDE validity and verification) edits are performed and the data are stored. DDPS edits records at the detail level, checking event-level information on the beneficiary, drug, costs, and other items. CMS maintains a complete, up-to-date listing of edits at

[https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20\(Part%20D\)~References](https://www.csscooperations.com/internet/csscw3.nsf/DIDC/FGSMOX8LWK~Prescription%20Drug%20Program%20(Part%20D)~References).

DDPS also provides simplified reporting from CMS to plan sponsors. Plan sponsors receive one complete report with all transactions and statuses listed. The report identifies which PDE data were accepted, and which were not, along with reason codes. Data tracking is improved by reporting complete results daily. Plan sponsors also receive periodic summary reports that aggregate the number of drug events submitted, rejected, and accepted.

After DDPS performs all necessary edits, the processed PDE data are forwarded to the Integrated Data Repository (IDR). The IDR stores PDE data and accumulates summary data for payment reconciliation, which is performed in the Payment Reconciliation System (PRS).

PRS creates a beneficiary/plan record for each beneficiary enrolled in a plan during the payment year and calculates reconciliation payments at the beneficiary and plan level. Specific reports issued from the IDR inform plans of their year-to-date financial values in preparation for reconciliation. CMS calls these management reports.

An outside contractor manages the data submission process for CMS and maintains a Customer Service and Support Center (CSSC) that provides customer service and support to data submitters. See <https://csscooperations.com/cssc>.

Refer to Section 12 of this Supporting Statement, under "Collection of Prescription Drug Event Data," for a detailed illustration of the data flow.

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

The collection of information will have a minimal impact on small businesses or other small organizational entities since the applicants must possess an insurance license and be able to accept risk. Generally, state statutory licensure requirements effectively prevent small organizations from accepting the level of risk needed to provide the pharmacy benefits required in the Medicare Prescription Drug Benefit program.

6. Less Frequent Collection

The PDE submission timeframes are described in 42 CFR 423.325. Section 423.325(a) codified long-standing guidance. In the April 27, 2006, Instructions on Requirements for Submitting Prescription Drug Event Data, CMS indicated that PDE data must be submitted to CMS electronically at least once a month. In addition, CMS issued more specific guidance on submission of original PDE data and corrections in the October 6, 2011 Health Plan Management System (HPMS) memorandum titled, [“Revision to Previous Guidance Titled ‘Timely Submission of Prescription Drug Event \(PDE\) Records and Resolution of Rejected PDEs.’”](#) Section 423.325(b) codified the PDE timeliness requirements for submitting PDE records for selected drugs (as described at section 1192(c) of the Act). For more information see 90 FR 15919 (April 15, 2025).

CMS believes that the PDE submission frequency described in the regulation minimizes burden yet allows for reimbursement to proceed in a timely and accurate manner. In accordance with the regulation, the PDE submission timeframes are as follows: Initial PDE data must be submitted within 30 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. Adjustments and deletions must be submitted within 90 calendar days of the Part D sponsor (or its contracted first tier, downstream, or related entity) discovering or receiving notification of an issue that requires a change to the previously submitted PDE record. A PDE record for a paid claim transaction associated with a PDE record that was previously rejected by CMS must be submitted at least once every 90 calendar days from receipt of a rejection until the PDE record is accepted unless the claim associated with the rejected PDE record is reversed or deleted, or the PDE record that was rejected is otherwise found to have been submitted in error. In addition, the regulations at 42 CFR 423.325(b) require that Part D sponsor submit initial PDE records for selected drugs within 7 calendar days from the date the Part D sponsor (or its contracted first tier, downstream, or related entity) receives the claim. See 90 FR 15792 (April 15, 2025) and 91 FR 17384 (April 6, 2026).

The PDE data is used in the Part D payment reconciliation, which CMS begins 6 months after the end of a coverage year. Also, consistent with 42 CFR 423.346(a)(2) and the timeframes described within, uses the PDE data to perform a global reopening of the reconciliation for that contract year.

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 monthly (with the exception of the requirements at 42 CFR 423.325(b));
- 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; or
- 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.

8. Federal Register Notice/Outside Consultation

The 60-day notice published in the Federal Register (XX FR XXXXX) on TBD.

Ongoing Communication

The table below is a summary of our specific communications and consultations with the industry since the package was last approved. The table breaks out events by Type, Date and Status.

Table 1. Communications with Industry

Type of Communication	Dates	Status
NCPDP Workgroup	On going	Active
PDE Training - 2025 Prescription Drug Event Participant Guide	July 17, 2025	Active
HPMS memorandum - 2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations_ 2025 prescription drug event file layout updates and pace guidance 50	March 8, 2024	Active
HPMS memorandum - May 2024 Updates to the Drug Data Processing System (DDPS)	May 10, 2024	Active
HPMS memorandum - Prescription Drug Event Submission Certification Requirements for 2025	May 10, 2024	Active
HPMS memorandum - Additional Information Regarding Prescription Drug Event Submission Certification for 2025	June 28, 2024	Active
HPMS memorandum - Prescription Drug Event Submission Certification Requirements for 2025 for PACE Organizations	July 12, 2024	Active
HPMS memorandum - End of Year Prescription Drug Event Submission Instructions to Facilitate Transition to 1000byte File Layout	November 22, 2024	Active
HPMS memorandum - 2026 Prescription Drug Event (PDE) File Layout Updates 2026 prescription drug event file layout updates	September 30, 2025	Active
HPMS memorandum - Clarification of Prescription Drug Event (PDE) Reporting Requirements for 340B Identification	May 1, 2026	Active

9. Payments/Gifts to Respondents

Respondents will not receive any payments or gifts for responding to this information collection. Submitting information using the prescribed CMS format is one of the requirements for participation in the Medicare Part D drug benefit program.

10. Confidentiality

The information provided by the plan or sponsor organizations regarding prescription drug events are protected and held confidential in accordance with 20 CFR 401.30. The information provided electronically and on forms will become part of the contracted organization's computer history, microfilm, and hard copy records retention system as published in the *Federal Register*, Part VI, "Privacy Act of 1974 System of Records" on September 20, 1976 (HI CAR 0175.04).

All electronic claims or drug events sent from pharmacies to PBMs or other third-party administrators and from them to plans constitute HIPAA-covered transactions. Any plan or sponsor organizations that utilize an electronic format for their drug data collection will need to convert to ANSI X12.

11. Sensitive Questions

Other than the information noted above in section 10 above, there are no questions of a sensitive nature. 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 (Adjusted)

The burden placed on Part D sponsors (contracts) associated with submitted PDE 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. The burden estimate is being revised to reflect more recent data regarding the number of sponsors, number of beneficiaries, and number of PDE records submitted.

- (a) PDE Data Submission: The amount of data that must be submitted is a function of the number of prescription drug events per beneficiary and the number of data elements per event. Based on CMS data from July 2026, CMS estimates that an annual average of 54,957,647 Medicare beneficiaries enroll in Part D prescription drug coverage. The average number of PDEs per year is 1,627,798,686 based on data from 2022, 2023, and 2024. To compute the average number of PDEs per beneficiary, we divide the average number of PDEs per year by the average number of beneficiaries enrolled per year. This computation leads to an average of 30 PDEs per beneficiary per year.
- (b) Number of Part D Contracts (Respondents): The average number of Part D contracts per year is 994 (based on 2022, 2023, and 2024 data).
- (c) Time Required to Process Data: The third factor that contributes to the burden estimate for submitting PDE data depends upon the time and effort necessary to complete data transaction activities. Since our regulations require Part D sponsors to submit drug event data 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 (Part C), the data transaction timeframes will be based on risk adjustment (Part C) and prescription drug industry experiences. Moreover, our PDE data submission format (as well as the drug industry's) will only support electronic formats. The drug industry's estimated average processing time for electronic data submission is 1 hour for 500,000 records. The risk adjustment estimated average annual electronic processing time cost per hour is \$17.75.

All three factors are reflected in Table 2 and illustrate the relationship between these results and the burden estimate.

Table 2. Annual Cost to Respondents Estimate for Active Collection of Information

FIELD	DESCRIPTION	DATA	NOTES
A	NUMBER OF RESPONDENTS	994*	994 is the annual average number of Part D contracts from 2022, 2023, and 2024
B	NUMBER OF MEDICARE BENEFICIARIES ENROLLED IN PART D PER YEAR	54,957,647**	Average number of Medicare beneficiaries enrolled in Part D
C	AVERAGE NUMBER OF PART D BENEFICIARIES PER CONTRACT	55,289	(B) divided by (A)
D	AVERAGE NUMBER OF PDES PER YEAR	1,627,798,686**	The average is based on annual average PDEs from 2022, 2023, and 2024
E	FREQUENCY OF RESPONSE	30 PDEs/per beneficiary per contract per year	(D divided by C) divided by A
F	NUMBER OF TRANSACTIONS PER HOUR	500,000	Drug industry's estimated average processing volume per hour
G	TOTAL ANNUAL TRANSACTION HOURS	3,256	(D) 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	\$57,794	(H) multiplied by (G)
J	AVERAGE COST PER PART D BENEFICIARY	\$0.001	(I) divided by (B)
K	ANNUAL COST TO RESPONDENTS	\$58.14	(J) multiplied by (C) Can also be calculated as (I) divided by (A)

*Data Source: Payment Reconciliation System Reports

**Data Source: CMS Integrated Data Repository

One-Time Burden Estimates Resulting from New Valid Values to Existing PDE Fields (New)

The burden associated with this one-time requirement is related to updating the systems and files to accommodate new valid values for PDE fields previously described under the previously approved ICR. Specifically, the following fields have been updated:

- Field 18 – DISPENSE AS WRITTEN (DAW) PRODUCT SELECTION CODE – new valid values:
 - 'A' = Multi-payer Brand/Reference Product Formulary Conflict
- Field 23 – PRESCRIBER ID QUALIFIER – new valid value:
 - '18' = No Prescriber ID, No Prescription Associated to the transaction (valid for OTC drugs only (Drug Coverage Status Code = 'O'))
- Field 24 – PRESCRIBER ID – new valid value:
 - '0' when Prescriber ID Qualifier = '18'
- Field 32 – CATASTROPHIC COVERAGE CODE– new value:

- 'N' = Attachment Point met; TrOOP subsequently reduced below the OOP threshold due to payment amounts from non-EGWP other payers reported in PLRO (reported by EGWPs only)
- Field 66 – PATIENT RESIDENCE– new valid value:
 - '14' = Homeless Shelter
- (a) Number of Part D Respondents: The average number of Part D Contracts offering a Part D plan per year (Row (B)) is 994 (based on 2022 – 2024 internal CMS data related to the number of contracts included in the annual Part D payment reconciliation).
- (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 2025 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 3).

Table 3. 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	65.38	65.38	130.76
Software Quality Assurance Analysts and Testers	15-1253	50.14	50.14	100.28
Database Administrators	15-1242	50.30	50.30	100.60
Computer Systems Analysts	15-1211	50.89	50.89	101.78

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

- On average, for each of the 994 Part D Contracts, 1 software developer working at \$130.76/hour spend 3 hours performing system maintenance with an aggregate per contract dollar burden of \$389,926.
 - Based on internal CMS data, there are about 994 Part D Contracts. The burden of update requires that 1 software developer will each spend 3 hours performing necessary redesigns. Therefore, the aggregate burden across all 994 Part D contracts is 2,982 hours (1 software developer x 3 hours a developer x 994 Part D Contracts).
 - Thus, the total cost is \$389,926 (2,982 hours x \$130.76 wage/hour)
- On average, for each of the 994 Part D Contracts, 1 Software Quality Assurance Analyst and Tester working at \$100.28/hour spend 1 hour performing system maintenance with an aggregate per contract dollar burden of \$99,678.
 - Based on internal CMS data, there are about 994 Part D Contracts. The burden of update requires that 1 Software Quality Assurance Analyst and Tester will spend 1 hours performing necessary redesigns. Therefore, the aggregate burden across all 994 Part D contracts is 994

- hours (1 Software Quality Assurance Analyst and Tester x 1 hour an analyst/tester x 994 Part D Contracts).
 - Thus, the total cost is \$99,678 (994 hours x \$100.28 wage/hour)
- On average, for each of the 994 Part D Contracts, 1 Database Administrator (DBA) working at \$100.60/hour spend 2 hours performing system maintenance with an aggregate per contract dollar burden of \$199,993.
 - Based on internal CMS data, there are about 994 Part D Contracts. The burden of update requires that 1 DBA will spend 2 hours performing necessary redesigns. Therefore, the aggregate burden across all 994 Part D contracts is 1988 hours (1 DBA x 2 hours a DBA x 994 Part D Contracts).
 - Thus, the total cost is \$199,993 (1988 hours x \$100.60 wage/hour)
- On average, for each of the 994 Part D Contracts, 1 Computer Systems Analyst working at \$101.78/hour spend 2 hours performing system maintenance with an aggregate per contract dollar burden of \$202,339.
 - Based on internal CMS data, there are about 994 Part D Contracts. The burden of update requires that 1 Computer Systems Analyst will spend 2 hours performing necessary redesigns. Therefore, the aggregate burden across all 994 Part D contracts is 1988 hours (1 Computer Systems Analyst x 2 hours an analyst x 994 Part D Contracts).
 - Thus, the total cost is \$202,339 (1988 hours x \$101.78 wage/hour)

Total Costs: The total cost for all 994 Part D Contracts is \$891,936 (\$389,926 + \$99,678 + \$199,993 + \$202,339) (see Table 4 below).

Table 4. One-Time Burden Estimates Resulting from New Valid Values to Existing PDE Fields

Estimated Number of Respondents	Burden per Response (hours)	Total Annual Burden (hours)/contract	Wages / hour (\$)	Total Estimated Labor Cost (\$)
994	3	2982	130.76	389,926
994	1	994	100.28	99,678
994	2	1988	100.60	199,993
994	2	1988	101.78	202,339
Total	8	7952		891,936

Information Collection/Reporting Instruments and Instruction/Guidance Documents

- Guidance for completing and submitting a PDE. No changes were made to this guidance. (Available at: [https://csscooperations.com/internet/csscw3.nsf/DIDC/GZEB9OUQJ9~Prescription%20Drug%20Program%20\(Part%20D\)~References](https://csscooperations.com/internet/csscw3.nsf/DIDC/GZEB9OUQJ9~Prescription%20Drug%20Program%20(Part%20D)~References))
- 2011 PDE Participant Guide related to PDE submission guidance for contract years prior to 2025. No changes were made to this guidance. (Available at: <https://csscooperations.com/api/files/cssc/pdeparticipantguide%20cameraready%20081811.pdf>)
- Revision to Previous Guidance Titled ‘Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs provides guidance on the

timeframes for submitting a PDE” is superseded by 42 CFR 423.325. (Previous guidance is available at: https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/hpms_memo_pde_timeliness_clarification_68.pdf)

- The following memorandum released on October 14, 2022, addresses how point of sale (POS)- remuneration must be applied and reported both through 2023 and from 2024 onwards and upcoming changes to PDE layout in 2024. This includes a change to the definition to field 40 and the addition of a new dollar amount field in 2025. Footnotes in the Memo explain the changes. No changes have been made to this guidance. “Reporting Estimated Remuneration Applied to the Point-of-Sale Price” (Available at: <https://www.cms.gov/files/document/erposamemo508g.pdf>)
- “PDE Reporting Instructions for Implementing the Cost Sharing Maximums Established by the Inflation Reduction Act for Covered Insulin Products and ACIP-Recommended Vaccines for Contract Year 2023,” released on September 26, 2022. No changes have been made to this guidance. (Available at: <https://www.cms.gov/httpseditcmgovresearch-statistics-data-and-systemscomputer-data-and-systemshpms-hpms-memos-archive/hpms-memos-wk-5-september-26-30>)
- 2025 Prescription Drug Event Participant Guide related to PDE submission guidance for contract years 2025 and later. (Available at: <https://csscooperations.com/cssc/did/ekkisl3y6v?cat=cssc-prescription-drug-program-part-d>)
- “New 2025 Prescription Drug Event (PDE) File Layouts (FINAL)” released on April 18, 2023, describes, after consideration of comments on the draft guidance, the final PDE file expansion and new file layout for contract year 2025. No changes have been made to this guidance. (Attached)
- “New 2025 Prescription Drug Event (PDE) FINAL File Layouts - FIELD UPDATES” released on October 31, 2023, describes updates to PDE file expansion and new file layout for contract year 2025. No changes have been made to this guidance. (Attached)
- “2025 Prescription Drug Event (PDE) File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations March 8, 2024. (Attached)
- “May 2024 Updates to the Drug Data Processing System (DDPS),” released on May 10, 2024. This memorandum addresses, among other items, PACE Organizations submission of ERPOSA on the PDE record. (Attached)
- “Prescription Drug Event Submission Certification Requirements for 2025,” released on May 10, 2024. (Attached)
- “Additional Information Regarding Prescription Drug Event Submission Certification for 2025,” released on June 28, 2024. (Attached)
- “Additional Information Regarding Prescription Drug Event Submission Certification for 2025,” released on July 12, 2024. (Attached)

- “End of Year Prescription Drug Event Submission Instructions to Facilitate Transition to 1000byte File Layout,” released November 22, 2024. (Attached)
- “2026 Prescription Drug Event (PDE) File Layout Updates_2026_prescription_drug_event_file_layout_updates,” released September 30, 2025. (Attached)
- “Clarification of Prescription Drug Event (PDE) Reporting Requirements for 340B Identification,” released May 1, 2026. Regarding CMS’s expectation, Part D sponsors must pass through the applicable Submission Clarification Code and Submission Type Code values provided by dispensers to the corresponding PDE fields, starting with CY 2025. This requirement allows for the submission of expanded values, including 340B. (Attached)

Submission Requirements

In order to make Medicare Part D payment in accordance with provisions of the Social Security Act, as previously described, CMS must collect a limited set of data elements for 100 percent of prescription drug claims or events from plans offering Part D coverage. In determining these requirements, we have incorporated feedback from industry and other stakeholders obtained by formal and informal means including the rulemaking process, Open Door Forums and other consultation. We used four criteria in selecting the required data elements:

- ability to pay plans timely and accurately;
- minimal administrative burden on CMS, Part D sponsors, PBMs, pharmacies, and others;
- legislative authority; and
- validity and reliability of the data elements requested, to ensure that the information will be useful.

We require that plans submit a PDE record for each dispensing event in a CMS defined format (PDE Inbound File Layout), which documents the final adjudication of the dispensing event. Since the pharmacy industry has an effective drug claims submission standard, which is electronically automated, we use the NCPDP version D.0 as the data format for PDE submissions, and we have added fields in anticipation of future updates to the NCPDP Telecommunications standard. PDE elements include data elements from the NCPDP billing transaction, data elements from the NCPDP billing response transaction, and CMS-defined data elements. Although a number of the statutory requirements of the Act are not available in the NCPDP data elements, we utilized the NCPDP format to construct the CMS-defined data elements to ensure minimal burden on plans.

The PDE Inbound File Layouts are available at <https://csscooperations.com/internet/csscw3.nsf/DID/M7XCJKG0JL>.

Collection of Prescription Drug Event Data

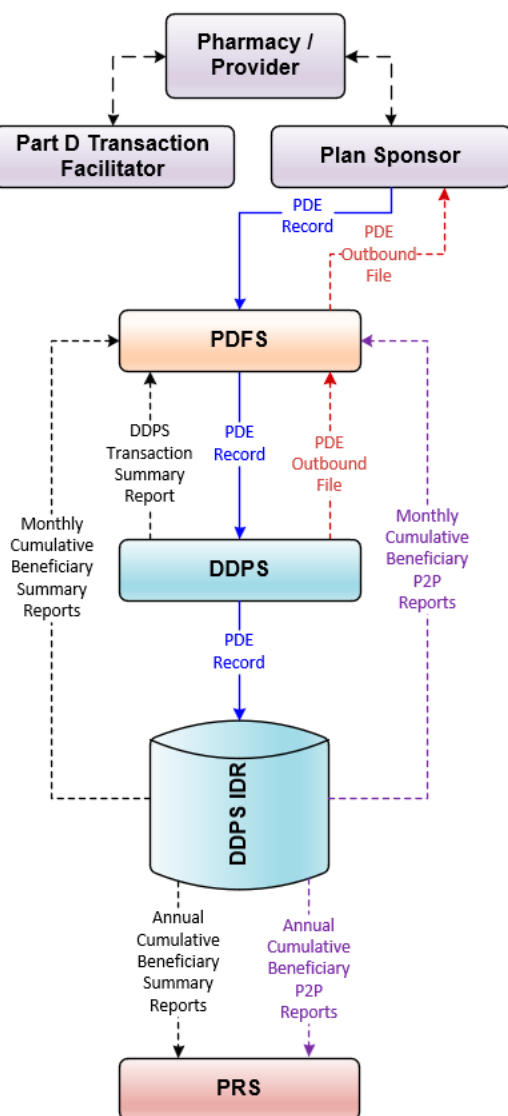
In most situations, the Part D sponsor or a designated third-party processor on the sponsor’s behalf (e.g., PBM) processes the prescription drug claim that has been submitted electronically by the network provider (e.g., pharmacy) and determines the applicable cost sharing to be made by the beneficiary. These are standard claims. Many electronic transactions may take place between plans, pharmacies, and intermediaries when a beneficiary fills a prescription. This

process allows determination of patient cost sharing at the point of sale by plan-adjudication of the claim and drives eventual plan payment to the pharmacy. Typically, the network providers provide billing transactions to plan sponsors in real-time.

In a limited number of situations, a beneficiary or other entity may submit a non-standard format claim, such as a paper claim to a plan sponsor or its third-party processor. The plan/processor then creates a PDE record from the claim to submit electronically to CMS in a non-standard format. (Note there are specific rules and exceptions regarding the completion of certain non-financial data elements.)

The following is an illustration of the PDE data flow:

Figure 1. PDE Data Flow



The following is a checklist of the PDE data flow:

- The pharmacy, physician, or other provider submits a claim to the plan sponsor. If necessary, the pharmacy generates a secondary claim to any other payers via the Part D Transaction Facilitator.
- Daily, the following tasks occur:
 - The Part D sponsor submits batches of PDE records daily Monday through Sunday to CMS via the PDFS.
 - PDFS performs format and validity checks on the Inbound PDE file. Once the file has passed front-end checks, PDFS sends the Inbound PDE file to DDPS. In addition, PDFS transmits the PDFS Response Report to Part D sponsors indicating file acceptance or rejection.
 - DDPS processes the PDEs and sends the PDE Outbound File to PDFS showing the acceptance or rejection of each PDE. In addition, PDFS receives a Transaction Error Summary Report that displays the count and rate for each error code found in the submitted PDE data. Both files are returned to the Part D sponsor via PDFS.
 - DDPS sends the Part D PDE records (accepted and rejected) to the IDR Warehouse.
- Monthly, DDPS IDR extracts Part D data for the Cumulative Beneficiary Summary Reports and Plan-to-Plan (P2P) Reports that are provided to Part D sponsors via PDFS. These management reports provide a summary of net accumulated totals for all dollar fields.
- Annually, DDPS provides accepted Part D PDE data to PRS for each Part D reconciliation. PRS creates a beneficiary/plan record for each beneficiary enrolled in a plan during the payment

13. Capital Costs

Any administrative costs incurred will be recouped through the bidding process and secured through the reinsurance and/or risk corridors processes. ***It is noteworthy that no capital costs are associated with this, and the average number of Part D contracts per year is 994 (based on 2022, 2023, and 2024 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. Cost to Federal Government

CMS has estimated that the total cost of the PDE data submission activities utilizing the PDFS and DDPS based on FY2026 funding amounts is approximately \$23.4 million.

Table 5. Total Cost of PDE Data Submissions

	PDFS	DDPS
Labor	\$2M	\$16.9M
Infrastructure (or other Direct Costs)	\$600K	\$3.9M
Total	\$2.6M	\$20.8M

15. Changes to Requirements and Burden (*Revised*)

Active Collection of Information and Associated Burden Estimates (Adjusted)

Our active average number of Part D contracts per year was 856 (based on 2019, 2020, and 2021 data). This ICR has been updated to reflect more current data, and the average number of Part D contracts per year is 994 (based on 2022, 2023, and 2024 data).

The average number of PDE submissions per year increased due to growth of Medicare beneficiaries enrolled in Part D and also because of a change in how we determined the number of PDE records submitted. Previously, the PDE count was final-action, non-delete PDE records for covered Part D drugs only. In this ICR, the PDE count is final-action, non-delete PDEs and includes both covered and non-covered drugs, because sponsors submit PDE records for non-covered drugs for over-the-counter drugs and drugs covered through the enhanced benefit. The total number of responses increased from 1,499,064,780 to 1,627,798,686. Therefore, the total estimated labor hours increased from 2,998 to 3,256, and the total costs increased from \$53,215 to \$57,794.

Table 6. Adjustments to the Annual Collection

	No. Respondents	Total Responses	Total Annual Time (hour)	Total Labor Cost (\$)
Active Burden	856	1,499,064,780	2,998	53,215
Updated Burden	994	1,627,798,686	3,256	57,794
Total Adjustment	+138	+128,733,906	+258	+4,579

One-Time Burden Estimates Resulting from New Valid Values to Existing PDE Fields (New)

CMS is accounting for the addition of two new valid values for PDE fields previously described under the previously approved ICR. We anticipate that this change would require Part D sponsors to make system changes related to updating the systems needed to accommodate the new valid values available on the PDE data collection form.

Table 7. Summary of Information Collection Requirements and Associated Burden Estimates

Citation	Item	Respondent	Number of Respondents	Number of Responses	Total Responses	Time per Respondent (hours)	Total Time (hours)	Total Estimated Labor Cost (\$)	Total Cost First Year (\$)
§§ 1860D-11(g)(5), 1860D-12(b)(3)(D), 1860D-14, 1860D-15, 1860D-22, 1860D-14A(c)(1)(C), 1860D-14C(c)(3), and 1860D-14D of the Act	Active Collection of Information (Adjusted)	Part D contracts	994	1,627,798,686	1,627,798,686	0.000002	3256	57,794	57,794

§§ 1860D-11(g)(5), 1860D-12(b)(3)(D), 1860D-14, 1860D-15, 1860D-22, 1860D-14A(c)(1)(C), 1860D-14C(c)(3), and 1860D-14D of the Act	One-Time Burden Estimates Resulting from New Valid Values to Existing PDE Fields (New)	Part D contracts	994	994	994	8	7952	various	891,936
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16. Publication/Tabulation Dates

The purpose of this data submission request is to support the payment of outpatient prescription drugs for beneficiaries who are members of Part D plans and who receive services under the Medicare Part D benefits 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. 0938-0982 (available at <https://www.reginfo.gov/public/Forward?SearchTarget=PRA&textfield=0938-0982&Image61.x=12&Image61.y=20>).

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.