Supporting Statement Part A
Part D Coordination of Benefits Data
(CMS-10171, OMB 0938-0978)

Background

The Centers for Medicare & Medicaid Services (CMS) is seeking approval to extend the ongoing collection of data required by the Medicare Prescription Drug, Improvement, and Modernization Act, as codified under sections 1860D-23 and 1860D-24 of the Social Security Act (the Act) regarding the coordination of Part D plan prescription drug coverage with other prescription drug coverage. This information collection request assists CMS, pharmacists, Part D plans, and other payers coordinate prescription drug benefits at the point-of-sale and track beneficiary True out-of-pocket (TrOOP) expenditures using the Part D Transaction Facilitator (PDTF).

This 2024/2025 iteration sets out an increase administrative burden from the previously approved iteration as a result of: (1) an increase in the number of Part D parent organizations, and (2) correcting burden associated with an existing information collection requirement.

A. Justification

1. Need and Legal Basis Section

Sections 1860D-23 and 1860D-24 of the Act require the Secretary to establish requirements for prescription drug plans to promote effective coordination between Part D plans and SPAPs and other payers. These Part D Coordination of Benefits (COB) requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464. Section 1860D-2(b)(4)(D)(ii) of the Act permits Part D plans to request information on third party insurance from beneficiaries and section 1860D-2(b)(4)(D)(i) of the Act authorizes the Secretary to establish procedures for determining if costs for Part D enrollees are reimbursed by other payers, and for alerting Part D plans about such arrangements. In particular, CMS' requirements relate to the following elements: 1) enrollment file sharing; 2) claims processing and payment; 3) claims reconciliation reports; 4) application of the protections against high out-of-pocket expenditures by tracking TrOOP expenditures; and 5) other processes that the Secretary determines.

Part D plans share data with each other and with CMS. The types of data collected for sharing include enrollment data, other health insurance information, TrOOP and gross drug spend and supplemental payer data.

CMS has worked with the pharmacy services industry to establish electronic standard transaction sets that enable Part D plans to electronically transfer COB information. These data transfers are conducted between pharmacies and Part D plans and among Part

D plans when a beneficiary changes plans during the contract year and to provide records of supplemental plan payments.

A CMS contracted entity, the PDTF serves an integral role in processing the transactions between entities. They are required to separate the transactions into 3 categories, which specify the entities involved as well as their stated purpose for processing the claim. It is important for the PDTF to accurately document the type of transaction being submitted, as any faulty information may cause delays in the coordination and administration of benefits.

Below is a table that contains the transaction types and general descriptions for transactions generated by Part D plans and processed through the PDTF.

Transaction Type	***Mandatory /Optional***	***Transaction Name***	***Description***	***Purpose***	***Involved Parties***
E1	*Optional (if beneficiary is not in possession of member ID Card*	*Pharmacy Eligibility Inquiry Transaction-enrollment data and other health insurance data*	*Sent by pharmacies with demographic data necessary to determine beneficiary enrollment in a Part D plan and in other coverage*	*Allow pharmacies to determine beneficiary's payer, the appropriate copayment and the correct bank routing number for pharmacies to submit claim*	*Pharmacies send transaction to PDTF. PDTF returns information to requesting pharmacy.*

Transaction Type	***Mandatory /Optional***	***Transaction Name***	***Description***	***Purpose***	***Involved Parties***
FIR	*Mandatory when beneficiaries change Part D plans within the plan year.*	*Financial Information Reporting Transaction-TrOOP and Gross drug spend data*	*To transfer beneficiary information, TrOOP and Total Drug Spend accumulated between all of a beneficiary's prescription drug coverage.*	*Allows a plan that is receiving a beneficiary mid-year to place the enrollee in the correct phase of the benefit; for example, if the deductible is paid in the*	*Financial Values transmitted from original plan to PDTF. PDTF conveys values to new plan. This function is called Automated TrOOP balance transfer (ATBT)*

				initial plan the FIR data would reflect that payment so the beneficiary would not need to pay it again while in the new plan	
Nx	*Mandatory*	*Information Reporting Transaction-supplemental payer payment data.*	*Provides Part D Plans with a records of Supplemental Coverage*	*Informs the Part D plan of payments made by supplementa l payers so that plan and beneficiary payment can be adjusted if needed*	*PDTF sends to Part D sponsors so TrOOP can be adjusted. Pharmacy processes claim and processor sends transaction which contains pharmacy claim request and payer response information to PDTF. PDTF sends to Part D sponsors so TrOOP can be adjusted.*

Part D plans are required to produce and process FIR and Nx transactions. However, there are two additional data sets that Part D plans need to collect that do not come from other Part D plans. These include:

- Beneficiaries with other health insurance coverage. Employer groups and supplemental payers report beneficiaries' coverage to CMS. CMS includes this information on Part D plans' membership files. Part D plans receive this information and generate communications to members to confirm the information received.
- State Pharmacy Assistance Program (SPAP) Enrollment. SPAP payments made are counted as TrOOP. Therefore, plans must be aware of SPAP payments. For this reason, Part D plans receive and record all payments that SPAPs make on behalf of their enrollees. CMS receives attestations from States to make sure that the SPAPs meet the requirements set forth by law.

2. Information Users

The collected information will be used by Part D plans, other health insurers or payers, pharmacies and CMS to coordinate prescription drug benefits provided to the Medicare beneficiary.

3. Use of Information Technology

The data collected is in addition to a number of systems and technologies developed at or since the beginning or the Part D program to assist with coordination of benefits. Coordination of benefits for Part D beneficiaries is essential when a beneficiary changes plans mid-year or has prescription benefits from sources in addition to Medicare. Beginning in CY 2009, the collection of information required some improved information technology. CMS in collaboration with the pharmacy services industry, through the National Council for Prescription Drug Programs (NCPDP) and the PDTF contractor automated the transfer of beneficiary financial information when a beneficiary changes Part D plans during the plan year. As mentioned in the table above, we refer to this process as Automated TrOOP Balance Transfer (ATBT). When a beneficiary switches plans during the plan year, the PDTF contractor requests the beneficiary's TrOOP-related balances from the dis-enrolling plan and any other prior plans in which the beneficiary was enrolled during the coverage year, and sends the reported balances to the enrolling plan. This improved process replaced the manual transfer of the information between the disenrolling and enrolling plans.

As for the existing Part D Coordination of Benefits (COB) requirements, most payers collect other health insurance information in order to properly bill the appropriate payer. Most pharmacies have established an electronic claims process utilizing a standard format established by the NCPDP and have the technology to assist in the coordination of benefits between Part D plans and other payers.

One such technology currently in use is the eligibility query, which enables the PDTF to provide coverage eligibility information to a requesting pharmacy when a Part D beneficiary presents him/herself at the pharmacy without a membership card. Prior to the PDTF contract, if a beneficiary entered a pharmacy without an insurance card, the pharmacist may attempt several times to submit claims in order to get a response indicating that the individual has drug coverage. The PDTF eligibility query process also assists the pharmacist when a beneficiary does not know what other health insurance coverage they have in addition to Part D.

4. Duplication of Efforts

This information is not currently being routinely collected by Medicare for purpose of point-of-sale benefits coordination and TrOOP tracking.

5. Small Businesses

This information collection will not have a significant impact on small businesses. With the implementation of Part D, small independent pharmacies have adopted the use of the electronic claims process for most aspects of billing and claim adjudication, using industry-wide standards to submit claims to Part D sponsors as well as to other insurers.

Reauthorizing this data collection will allow continued coordination of benefits for enrollees using smaller pharmacies as well as larger chain, retail, or mail order pharmacies.

6. Less Frequent Collection

Failure of the Part D sponsors, States and other payers to submit these data will result in Part D plans not meeting the coordination requirements as set forth by the Secretary in accordance with 1860D-23 of the Act. E1 and Nx transactions are to be processed in real time and as circumstances call for them. In other words, pharmacies may submit E1s when beneficiaries present a prescription at the pharmacy counter and are in need of coverage information. Part D sponsors must submit FIR data within 15 days of the effective date of the new enrollment or, if later, the date of the initial Automatic TrOOP Balance transaction. Specifically, entities that fail to submit this information within the timelines specified by CMS will:

- Impede CMS' process for tracking and reporting TrOOP spending incurred by Medicare beneficiaries in Part D, potentially impacting how quickly a beneficiary moves through the benefit coverage levels;
- Reduce CMS' ability to work with the pharmacy services industry to provide improved customer support to Medicare beneficiaries and administration of the Part D benefit at the point-of-sale; and
- Increase the possibility that Part D benefits may be withheld from the beneficiary.

7. Special Circumstances

Due to the nature of COB under Part D, the Part D sponsors use the PDTF as the vehicle to exchange standardized information with each other on a real time or daily batch basis. This enables Part D sponsors to adjust the tracking of gross covered drug and TrOOP costs continuously in real time.

Otherwise, 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-inaid, 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

The 60-day notice published in the Federal Register 10/21/2024 (89 FR 84154).

We received comments from 3 commenters. Commenters provided many suggestions to improve the overall COB process and Section 111 information reporting requirements which were outside the scope of this information collection. Some comments referred to burden associated with the annual COB notification letters to beneficiaries. We revised burden accordingly in section 12 and further describe the changes in section 15 of this supporting statement. In light of the comments received, we have updated estimates for the Part D sponsors' burden associated with mailing COB notification letters and updating OHI in ECRS based on beneficiary responses. Additionally, we have added burden associated with beneficiary responses to COB notification letters.

The 30-day notice published in the Federal Register 5/12/2025 (90 FR 20166).

Outside Consultations

As a member of the NCPDP, CMS meets regularly with members of the NCPDP to establish and revise electronic transaction standards with the pharmacy services industry given the implementation of the Medicare prescription drug benefit. NCPDP work groups meet every other week as needed. Necessary changes are presented and ratified during the quarterly work group meetings, See https://standards.ncpdp.org/Work-Groups.aspx. CMS adopts changes as recommended by the NCPDP. CMS has been in

constant consultation with pharmacy services industry experts through NCPDP regarding the coordination of Part D benefits at the point-of-sale.

9. Payment/Gift to Respondent

Part D plans are required to comply with all applicable statutory and regulatory requirements including those requiring COB (1860D-23 and 1860D-24). No gifts or payments are provided for the participation of collecting this data. The collected information will be used by Part D plans, other health insurers or payers, pharmacies and CMS to coordinate prescription drug benefits provided to the Medicare beneficiary.

10. Confidentiality

The information submitted by the Part D sponsors is not proprietary. Pricing data will not be requested as part of the coordination of benefits. Part D sponsors are required to make sure that all necessary and proper precautions will be taken for securing protected health information (PHI) shared among payers for the purpose of coordinating benefits.

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

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

To account for individual beneficiaries' hourly wage, unlike our private sector adjustment to the respondent hourly wage, we are not adjusting this figure for fringe benefits and overhead since the individuals' activities would occur outside the scope of their employment.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Computer System	15-1211	49.90	49.90	99.80

Analyst				
Business Operations Specialists, All Other	13-1199	42.85	42.85	81.70
Pharmacy Technicians	29-2052	20.83	20.83	41.66
All Occupations	00-0000	20.71	n/a	n/a

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 overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates (PDs and MA-PDs)

The Part D organization's collection of supplemental payer information from the beneficiary and PDTF for the purposes of calculating TrOOP will require the following levels of efforts for current enrollment and payer systems:

The PDTF sends N transactions to the Part D sponsors who ensure that the correct TrOOP amounts are applied to beneficiary TrOOP accumulators. Based on data from the PDTF for 2024, 670,491,000 N transactions were sent from the PDTF to Part D sponsors. N transactions are generally processed by computer systems in an automated manner. For maintenance of the N transaction processing system by Part D sponsors we estimate an annual burden of 93,198 hours (670,491,000 x 0.000139 hours) (Estimate 1)

Part D sponsors send their enrollees annual COB notification letters which contain the OHI information that Part D sponsors received from CMS. Enrollees must confirm that the OHI information the Part D sponsor received from CMS is accurate and respond to their Part D with any updates, as necessary. Part D sponsors will then notify CMS of the enrollee's OHI changes to CMS through the CMS Electronic Correspondence Referral System (ECRS). Part D sponsors send COB notification letters only to enrollees for whom CMS has sent OHI to the Part D sponsors or new enrollees who indicated on their Part D plan application that they have some other source of other prescription drug coverage. Based on conversations with Part D plans and PBMs though the NCPDP task group, it is estimated that approximately 10 percent of Part D enrollees have some source of other prescription drug coverage. As of February 2025, there were 55,565,738 Part D enrollees.[1] We therefore estimate 5,556,574 COB notification letters (55,565,738 x 0.10) mailed annually.

1 Accessible at https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-advantagepart-d-contractand-enrollment-data/monthly-contract-and-enrollment-summary-report

We calculate non-labor costs associated with sending COB notification letters. Enrollees may opt in to receiving communication materials electronically rather than via hard-copy mailings; however, consistent with informal communication from stakeholders for other required documents, we assume enrollees prefer hard-copy mailings. Costs for hard-copy mailings include paper, toner, envelopes, and postage.

- Cost of paper: We assume $3.50 for a ream of 500 sheets. The cost for one page is $0.007 ($3.50/500 sheets).
- Cost of toner: We assume a cost of $70 for 10,000 pages. The toner cost per page is $0.007 ($70/10,000 pages).
- Cost of envelopes: We assume a cost of $440 for 10,000 envelopes. The cost per envelope is $0.044.
- Cost of postage: The current cost of first-class metered mail is $0.64 per letter up to 1 ounce. We are using metered mail because these notifications contain confidential beneficiary information and therefore a bulk mailing cannot be used.

  A sheet of paper weights 0.16 ounces (5 pounds/500 sheets x 16 ounces/pound). We estimate each mailing to consist of 2 pages or 0.32 ounces, so no additional postage for mailings in excess of 1 ounce is anticipated.
- Aggregate cost per mailing: $0.7120 ([$0.007 for paper x 2 pages] + [$0.007 for toner x 2 pages] + $0.64 for postage + $0.044 for per envelopes).

We estimate the total annual mailing cost at $3,956,281 ($0.7120 per letter x 5,556,574 COB notification letters). (Estimate 2)

Based on their enrollees' responses, Part D sponsors report OHI changes to CMS by entering updates to OHI information into ECRS (42 CFR 423.462(b) and 42 CFR 423.464(h)). We estimate 0.0833 hours for a business operations specialist to submit each update for a total burden of 4,629 hours (55,566 x 0.833 hours) for an annual cost of $378,189. (Estimate 4)

The Automatic TrOOP Balance Transfer (ATBT) involves FIR transactions sent electronically between Part D plan and the PDTF and are generally processed by computer systems in an automated manner. Based on data from the PDTF for 2024, 318,827,000 FIR transactions were sent at 0.000139 hours per transaction. Therefore, for maintenance of the ATBT function by Part D sponsors we estimate 43,317 hours for all plan sponsors (Estimate 5).

Burden Estimates (Beneficiaries)

Beneficiaries are instructed to verify the OHI information on the notification letter and respond to their Part D sponsor if updates are needed (42 CFR 423.32(b)(2)). Since the number of other payers participating in voluntary data sharing agreements with CMS have grown since the start of the Part D program, there are few beneficiaries for whom CMS does not already have accurate OHI information. We estimate that one percent of beneficiaries with OHI will respond to their Part D sponsor with updates and that each response will take the beneficiary 0.25 hours. We therefore estimate the annual burden for beneficiaries to respond to OHI notification letters to be 13,892 hours (5,556,574 x 0.01 x 0.25 hours) at a cost of $287,703 (13,892 hours x $20.71/hour) (Estimate 3)

Burden Estimates (Pharmacies)

According to the National Community Pharmacists Association, as of 2024, there are approximately 19,000[2] independent pharmacies and the National Association of Chain Drug Stores states that there are approximately 40,000[3] chain drug stores for a total of 59,000 pharmacies total.

According to data from the PDTF, 57,438,000 eligibility transactions from were processed in 2024. We estimate it will take a pharmacy technician 0.0028 hours to query the system for each eligibility transaction. We estimate the annual burden on the pharmacies is 160,826 hours (57,438,000 x 0.0028 hours). hours). (Estimate 6)

Burden Estimates (States)

SPAPs submit attestations for CMS review to determine whether they meet requirements to qualify their payments as TrOOP eligible. As of 2024, there are 23 SPAP attestations submitted in CMS' Health Plan Management System (HPMS). See Attachment 1 for the collection instrument - SPAP Attestation Submission. We estimate that it will take each
SPAP two hours to complete and submit the template form for a total of 46 hours (23 States x 2 hours) (Estimate 7)

2 Accessible at https://ncpa.org/newsroom/news-releases/2024/10/27/ncpa-releases-2024-digest-report

[3] Accessible at https://www.nacds.org/about/mission/

Annual Burden Summary

Requirement	Respondents	Total Responses	Time per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting ($/hr)	Total Cost ($)
Processing claims through TrOOP facilitator (Receiving N transactions) (Burden Estimate 1 - Part D plans)	299	670,491,000	0.000139	93,198	99.80	9,301,160
Mail COB notification letters notices to enrollees with OHI (Burden Estimate 2- Part D plans)	299	5,556,574	n/a	n/a	n/a	3,956,281 *(non-labor costs)*
Respond to COB notification letter (Burden Estimate 3 - Beneficiaries)	55,566	55,566	0.25	13,892	20.71	287,703
Enter OHI changes in ECRS (Burden Estimate 4 - Part D plans)	299	55,566	0.0833	4,629	81.70	378,189
ATBT exchanges and updates (i.e. FIR) transactions (Burden Estimate 5 - Part D plans)	299	318,827,000	0.000139	43,317	99.80	4,323,037
Eligibility Queries (i.e. E1 transactions) (Burden Estimate 6 - Pharmacies)	59,000	57,438,000	0.0028	160,826	41.66	6,700,011
State Attestations (Burden Estimate 7 - States)	23	23	2	46	48.30	2,222
TOTAL	115,785	994,985,729	varies	315,908	varies	24,948,603

13. Capital Costs

There are no capital costs reported at this time related to the collection of this data.

14. Cost to Federal Government

The PDTF contract, which is facilitated by the contractor RelayHealth –

- Receives and maintains eligibility data from CMS;
- Supports query from pharmacy regarding eligibility, include in message on the E1 segment of the NCPDP Telecommunication standard;
- Captures primary response and secondary payer claim submission; • Routes N transactions to Part D plans (TrOOP costs);
- Provides CMS with copies of the N transactions (at least in batch).

The estimated cost of the PDTF contract is $27 million per annum. This estimate is based upon the current per annum contract costs.

15. Changes to Burden

Based on revisions to this collection, we calculate a decrease in annual burden from 938,968 hours to 315,908 hours and a decrease in cost from $35,214,239 to $24,948,603. This is despite an increase in the number of responses from 748,566,570 to 994,985,729. Our estimates reflect actual data from the PDTF and we believe number of eligibility (E1) transactions (333,178,054 in the previously approved collection vs. 57,438,000 according to 2024 data from PDTF) disproportionally affected the total burden calculations for this collection in the previous revision. The increased number of responses also reflects 2024 data from PDTF for Nx (Estimate 1) and ATBT FIR (Estimate 5) transactions as well as responses associated with the corrected burden associated with mailings for COB notification letters and Part D sponsors updating OHI in ECRS. Although the number of responses increased, most of the electronic transactions are processed automatically so there was still a net decrease in time and cost burden due to our overall revisions. We also updated the number of Part D parent organizations and the wages associated with certain tasks. Specifically, a Medical Transcriptionist was not an appropriate job category for the previous burden estimate “Mail OHI notices to benes and enter changes in ECRS”. Previously this burden was calculated at merely 0.0166 hours per parent organization for a total annual burden of 4.96 hours (0.0166 hours * 299 parent organizations) which appeared to be erroneous since OHI information must be entered for each beneficiary and not per organization. The previous estimate also failed to account for the non-labor burden associated with mailing “OHI notices” (i.e., COB notification letters) to beneficiaries. We also updated the labor burden associated with entering OHI updates in ECRS, which would be completed by a business operations specialist at a Part D sponsor organization. Correcting this calculation resulted in as addition 55,556 responses and 4,629 hours of burden (Estimate 4). We also accounted for beneficiary burden associated with responding to annual OHI notification letters (Estimate 3). These updates are not a result of new requirements, rather, have been longstanding

requirements that were not adequately captured in this collection previously. There was also an increase in the number of SPAPs from 13 to 23 since the previously approved version of this collection.

Annual Burden for this Collection	Approved	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Responses	994,985,729	+246,419,159	0	748,566,570
Time (Hours)	315,908	-623,060	0	938,968
Cost (Dollars)	24,948,603	-10,292,636	0	35,241,239

16. Publication/Tabulation Date

The data is collected in order to meet statutory requirements for Part D plans to coordinate benefits. The data is not shared with others outside of CMS not involved with coordination of benefits, nor is the data shared with the public.

17. Expiration Date

The expiration date of this data collection authorization is displayed on all approved collection instruments.

18. Certification Statement

There are no exceptions to the certification statement.