

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 iteration sets out an increase administrative burden from the previously approved iteration as a result of the factor including; (1) an increase in the number of Part D parent organizations.

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. 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.

<i>Transaction Type</i>	<i>Mandatory /Optional</i>	<i>Transaction Name</i>	<i>Description</i>	<i>Purpose</i>	<i>Involved Parties</i>
<i>E1</i>	<i>Optional (if beneficiary is not in possession of member ID Card</i>	<i>Pharmacy Eligibility Inquiry Transaction-enrollment data and other health insurance data</i>	<i>Sent by pharmacies with demographic data necessary to determine beneficiary enrollment in a Part D plan and in other coverage</i>	<i>Allow pharmacies to determine beneficiary's payer, the appropriate copayment and the correct bank routing number for pharmacies to submit claim</i>	<i>Pharmacies send transaction to PDTF. PDTF returns information to requesting pharmacy.</i>
<i>FIR</i>	<i>Mandatory when beneficiaries change Part D plans within the plan year.</i>	<i>Financial Information Reporting Transaction-TrOOP and Gross drug spend data</i>	<i>To transfer beneficiary information, TrOOP and Total Drug Spend accumulated between all of a beneficiary's prescription drug coverage.</i>	<i>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 initial plan the FIR data would reflect that payment so the beneficiary would not need to pay it again while in the new plan</i>	<i>Financial Values transmitted from original plan to PDTF. PDTF conveys values to new plan. This function is called Automated TrOOP balance transfer (ATBT)</i>

<i>Nx</i>	<i>Mandatory</i>	<i>Information Reporting Transaction – supplemental payer</i>	<i>Provides Part D Plans with a records of Supplemental Coverage</i>	<i>Informs the Part D plan of payments made by supplemental payers so that</i>	<i>PDTF sends to Part D sponsors so TrOOP can be adjusted. Pharmacy processes claim and processor</i>
		<i>payment data.</i>		<i>plan and beneficiary payment can be adjusted if needed</i>	<i>sends transaction which contains pharmacy claim request and payer response information to PDTF. PDTF sends to Part D sponsors so TrOOP can be adjusted.</i>

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.
- 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 of 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-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register Notice/Outside Consultation

Federal Register

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.ncdp.org/Work-Groups.aspx>. CMS adopts changes as recommended by the NCPDP. Generally, changes have a long lead time. For example, current changes in the transaction standard sets will be implemented in 2025 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.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer System Analyst	15-1211	49.90	49.90	99.80
Healthcare Support Workers, All Other	31-9099	22.60	22.60	45.20
Medical Transcriptionists	31-9094	18.79	18.79	37.58
Pharmacy Technicians	29-2052	20.83	20.83	41.66

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:

To process the information from the PDTF, we estimate an annual burden of hours 93,323 (299 organizations¹ x 2,242,445 responses per respondent x .000139 hours per

¹ The CMS data system which collects information on Part D sponsor applications, HPMS, indicates that there were 299 MA-PD and PDP organizations in 2024 .

response). The PDTF sends this information to the Part D sponsors who ensure that the information is assimilated into beneficiary records. (Estimate 1)

Mailing Beneficiary Other Health Information (OHI) notices and entering any reported OHI information takes approximately 0.0166 hours or 1 minute per sponsor for a total of 5 hours for all Part D organizations. (Estimate 2)

For maintenance of the Automatic TrOOP Balance Transfer (ATBT) function by Part D sponsors we estimate 28,681 hours for all plan sponsors (Estimate 3).

Burden Estimates (Pharmacies)

According to the National Community Pharmacists Association there are approximately 19,400¹ independent pharmacies and the National Association of Chain Drug Stores states that there are 40,000² chain drug stores for a total of 59,000 stores total.

We estimate the pharmacy technician may need to query the PDTF for beneficiary eligibility information an average of 5,500 times per year. It will take the pharmacy technician an average of 10 seconds to query the system. We estimate the annual burden on the pharmacies is 832,277.60 hours (59,000 pharmacies x 5,038 responses x .0028 hours). (Estimate 4)

Burden Estimates (States)

CMS reviews attestations from SPAPs to determine whether they meet requirements to qualify their payments as TrOOP eligible. We estimate that it will take each SPAP two hours to complete and submit the template form for a total of 26 hours (13 States x 2 hours) (Estimate 5)

¹ Accessible at <http://www.ncpanet.org/home/find-your-local-pharmacy>

² Accessible at <https://www.nacds.org/about/mission/>

Annual Burden Summary

Requirement	Frequency	Respondents	Total Responses	Burden per Response	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)	2,242,445	299	670,491,000	0.000139	93,198	99.80	\$ 9,301,160
Mail OHI notices to benes and enter changes in ECRS (Burden Estimate 2 - Part D plans)	Once per year	299	299	0.0166	4.96	37.58	\$ 186.40
ATBT exchanges and updates transactions (Burden Estimate 3 - Part D plans)	1,070,234	299	320,000,000	0.0001	32,000.00	99.80	\$3,193,600
Eligibility Queries (Performed by Pharmacy Technicians) (Burden Estimate 4 Pharmacies)	5,038	66,133	333,178,054	0.0028	932,899	41.96	\$39,144,442
State Attestations (Burden Estimate 5 - States)	Once per year	13	13	2	26	48.30	\$1,256
TOTAL	varies	67,043	1,323,669,366	varies	1,058,128	varies	\$51,640,644.44

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;
- Supports query from pharmacy regarding eligibility, include in message on the E1 segment of the NCPDP v. D.0;
- 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

This package shows an increase in burden from 938,968 hours to 1,058,128 hours, a net change of 119,160 additional hours. The increase in hours can be attributed to an increase in number of MA-PDP and PDP Organizations, in addition to E1, TrOOP Facilitator, and ATBT Transactions. The number of responses increased from 748,566,570 to 1,323,669,366, also because of the increase in number of MA-PDP and PDP Organizations, and the respective transactions. The cost for this IC changed from \$35,241,239 to \$51,640,644, an increase of \$16,399,405, which can be attributed to increase in labor rate categories and greater number of MA-PDs and PDPs.

	Approved	Change Due to Adjustment in Agency Estimate	Change Due to Potential Violation of the PRA	Previously Approved
Annual Number of Responses for this IC	1,323,669,366	+ 575,102,796	0	748,566,570
Annual IC Time Burden (Hours)	1,058,128	+ 119,160	0	938,968
Annual IC Cost Burden (Dollars)	\$51,640,644	+ 16,399,405	0	\$35,241,239

Decrease in the number of State Programs. The number of State Pharmaceutical Assistance Programs (SPAPs) decreased from 19 programs in 2020 to 13 in 2024. This decrease did not offset the total burden for this ICR.

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

18. Certification Statement

There are no exceptions to the certification statement.

