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 2017 iteration sets out a decrease in administrative burden (-4,267,067 hours = (938,061 proposed hours - 5,205,128 hours relative to the 2013 authorization) as a result of several factors, including: (1) process improvements including additional automation, (2) stable transaction sets with have eliminated programming costs, (3) experience requirements, (4), a decrease in the number of state programs, (5) computerization of the process which CMS uses to communicate with State Pharmacy Assistance Programs (SPAPs) and (6) the elimination of lump sum programs.

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 industry to establish standard transaction sets that enable Part D plans to perform COB electronically to transfer information 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 a pivotal 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.*
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 initial plan the FIR data would reflect that payment so the beneficiary would not need to pay it again while in the new plan*	*Financial Values transmitted from original plan to PDTF. PDTF conveys values to new plan. This function is called Automated TrOOP balance transfer (ATBT)*
Nx	*Mandatory*	*Information Reporting*	*Provides Part D Plans*	*Informs the Part D plan*	*PDTF sends to Part D sponsors so*

		Transaction – supplemental payer payment data.	*with a records of Supplemental Coverage*	*of payments made by supplemental payers so that plan and beneficiary payment can be adjusted if needed*	*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 also two data sets that Part D plans need to collect in order to perform that do not come from other Part D plan. These include:

- Beneficiaries with Other health insurance. 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 generates communications to member to confirm the information received.
- SPAP Enrollment. SPAPs 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 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 section 1A 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 disenrolling 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 current 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 pharmaceutical 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

The 60-day notice published in the Federal Register on December 19, 2016 (81 FR 91937). No comments were received.

The 30-day notice published in the Federal Register on February 21, 2017 (82 FR 11222). No comments were received.

Outside Consultations

As a member of the National Council for Prescription Drug Programs (NCPDP), CMS meets regularly with members of the NCPDP to establish and revise electronic transaction standards with the 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://www.ncpdp.org/Events/Work-Group-Meetings. 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 2023. CMS has been in constant consultation with industry experts through NCPDP regarding the coordination of Part D benefits at the point-of-sale.

9. Payment/Gift to Respondent

There is no payment/gift to respondent.

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 2016 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	15-1121	44.05	44.05	88.10

Healthcare Support Workers, All Other	31-9099	18.13	18.13	36.26
Medical Transcriptionists	31-9094	17.86	17.86	35.72
Pharmacy Technicians	29-2052	15.47	15.47	30.94

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 Part D Transaction Facilitator 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 63,700 hours (296 organizations[1] x 1,548,233 responses per respondent x .000139 hours per 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 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 23,000[2] independent pharmacies and the National Association of Chain Drug Stores states that there are 40,000[3] chain drug stores for a total of 63,000 stores total.

We estimate the pharmacy technician may need to query the Part D Transaction Facilitator system 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 5,112,800 hours (63,000 pharmacies x 4,958 responses x .0028 hours). (Estimate 4)

[1] The CMS data system which collects information on Part D sponsor applications, HPMS, indicates that there were 296 MA-PD and PDP organizations in 2017.
[2] Accessible at http://www.ncpanet.org/home/find-your-local-pharmacy
[3] Accessible at https://www.nacds.org/about/mission/

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 44 hours (22 States x 2 hours) (Estimate 5)

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)	1,548,233	296	458,277,000	0.000139	63,700	88.10	5,611,970
Mail OHI notices to benes and enter changes in ECRS (Burden Estimate 2 - Part D plans)	Once per year	296	296	0.0166	5	35.72	178.60
ATBT exchanges and updates transactions (Burden Estimate 3 - Part D plans)	423,986	296	225,075	0.0001	6,662	88.10	586,922
Eligibility Queries (Performed by Pharmacy Technicians) (Burden Estimate 4 Pharmacies)	4,958	63,000	312,354,000	0.0028	867,650	30.46	26,428,619
State Attestations (Burden Estimate 5 - States)	Once per year	22	22	2	44	42.90	943.80
TOTAL		63,910	770,856,393	varies	938,061	varies	$33,042,132

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 Part D Transaction Facilitator contract –
- 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 Part D Transaction Facilitator contract is $9 million per annum. This estimate is based upon the current per annum contract costs.

15. Changes to Burden

This package shows a decrease in administrative burden of 4,267,067 hr as a result of several factors:

1. *Process Improvements.* CMS, in conjunction with the industry and NCPDP, made a number of improvements to the ATBT process including revising the scheduling of the transactions to cover the entire 36 month coordination of benefits period required by regulation. This automation eliminated the need for manual spreadsheet transmission and human intervention in the process. It also eliminated the risk of a PHI breach due to manual transmission of data through email. This resulted in an increase in the overall volume of ATBT transactions from our previous estimates.
2. *Stable transaction sets*. The standard transactions that are required for COB will be unchanged. CMS adopts industry standards specified by the industry through the NCPDP. The current NCPDP standards will not change until 2023. Part D sponsors have already programmed their systems to comply with the existing standards and would not need to repeat this step for this reauthorization.
3. *Experience requirements*. CMS found that new Part D sponsors often make administrative errors that are of detriment to the beneficiaries. Therefore, beginning in 2016, new Part D sponsors were required to have arrangements with experienced downstream entities that have Part D COB experience. This requirement promotes overall program efficiency. The provisions were finalized in a regulation published in May 2014, so they would have first been applied in 2015 during the CY2016 application review cycle. (See 423.504(b)(8) and (9)).
4. *Decrease in the number of State Programs*. The number of State Pharmaceutical Assistance Programs (SPAPs) decreased from 39 programs in 2015 to 22 in 2016. Part D plans are required to coordinate with applicable state assistance

programs and a smaller number of these programs decreases the aggregate burden.

5. *Elimination of Lump Sum Programs*. No SPAPs employ the lump sum benefit structure which eliminates negotiations and the manual process associated with administering these plans.

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 will be displayed.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

Not applicable. This information collection does not employ statistical methods.