Supporting Statement for Collecting Benefit Coordination Data
CMS-10171, OCN 0938-0978

Background

The Centers for Medicare & Medicaid Services (CMS) is seeking approval of a collection of data required by the Medicare Prescription Drug, Improvement, and Modernization Act, as codified in to law at section 1860D-23 and 1860D-24 of the Social Security Act (the Act) in order to coordinate Part D plan prescription drug coverage with other prescription drug coverage. This collection request will assist CMS, Part D plans and other payers with coordination of prescription drug benefits at the point-of-sale and tracking of the beneficiary's True out-of-pocket (TrOOP) expenditures using the Part D Transaction Facilitator (PDTF).

A. Justification

1. Need and Legal Basis Section

Section 1860D-23 and 1860D-24 of the Act requires the Secretary to establish requirements for prescription drug plans to ensure the effective coordination between Part D plans, State pharmaceutical Assistance programs and other payers. In particular, the requirements must 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.

These requirements have been codified into the Code of Federal Regulations at 42 CFR 423.464.

2. Information Users

This 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

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. 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 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.

We continue to believe that the eligibility query, that enables the PDTF to provide eligibility information to the pharmacy when a Part D beneficiary presents him/herself at the pharmacy without a membership card, save pharmacies time. 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 collected.

5. Small Businesses

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

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. Specifically, entities that fail to submit this information will:

- impede CMS' process for tracking and reporting TrOOP spending incurred by Medicare beneficiaries in Part D;
- 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

There are no special circumstances regarding the collection of this information.

8. Federal Register Notice/Outside Consultation:

The 60-day Federal Register notice published on July 5, 2013 (78 FR 40482). No comments were received.

In a notice of proposed rulemaking dated August 3, 2004, CMS considered a number of options for facilitating the exchange of data needed in order for Part D plans to track a beneficiary's True out-of-pocket (TrOOP) costs, and discussed the two options for operationalizing the data exchange related to the Part D coordination of benefits system and TrOOP accounting: Option 1 gave sole responsibility for TrOOP tracking to the Part D plan, and Option 2 was for CMS to procure a contractor to establish a single point of contact between payers (primary and secondary) for the TrOOP facilitation process. On January 28, 2005, CMS published the final regulation on the Medicare Prescription Drug Benefit. As part of that regulation, CMS responded to a large number of public comments regarding the establishment of a single-point of contact between payers, primary or secondary, in order to track the true out-of-pocket expenditures of a Part D beneficiary.

In 2005, CMS awarded a contract to NDC Health (dba Relay Health) to act as the TrOOP (now Part D Transaction) Facilitation Contractor. The Part D Transaction Facilitation (PDTF) contractor is responsible for establishing procedures for responding to eligibility queries at POS, identifying costs that are being reimbursed by other payers, and for alerting Part D plans about such transactions. CMS continues to contract with NDC Health to provide facilitation services. Beginning in 2009, the PDTF contractor also supports the transfer of TrOOP-related information between Part D plans when beneficiaries switch plans during the contract year.

As a member of the National Council for Prescription Drug Programs (NCPDP), CMS also meets regularly with members of the NCPDP to establish and revise electronic transaction standards with the industry given the implementation of the new Medicare prescription drug benefit. 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.

11. Sensitive Questions

Questions of a sensitive nature are not being asked.

12. Burden Estimates

2,402,582 is the total number of responses submitted for approval and 240 is the total burden hours per response.

Respondent	Burden Estimate
PDs and MA-PDs – • Collection of other payer coverage information from beneficiary. • Collection of claims information from Transaction Facilitator (N1, N2, N3 transaction). • Lump sum payments • Automated TrOOP Balance Transfer	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: • Revisions to current enrollment and payer systems – Part D plan's systems must receive enrollment information and N1, N2, and N3 transactions from the Part D Transaction Facilitator. We estimate that it will take each organization 60 hours to complete the system changes. There will be approximately 10 new organizations for an annual estimated burden of **600** hours for all new plans. (10orgs. x 1 response x 60 organizations). • Processing information from the Part D Transaction Facilitator-- The annual estimate is based on the actual number of responses for all Part D organizations in 2012. 211 organizations x 2,172,000 responses per respondent x .000139 = 63,652 burden hours. Entering other payer or other health insurance (OHI) enrollment information into the plans' systems. Entering the OHI enrollment information will take approximately .0166 hours or 1 minute per sponsor for a total of 3 hours for all Part D organizations. Lump sum approach for State Pharmaceutical Assistance Programs – PDPs and MA-PDs will need to develop a bid response to RFPs from states that adopt the lump sum payment approach. We estimate that an initial 60 hours per sponsor will be dedicated to this process or (60 hours x 211organizations x 1 response.) **12,660** hours for all plan sponsors. • Automatic TrOOP Balance Transfer (ATBT): For systems programming and maintenance for ATBT, we estimate 8,619 hours for all plan sponsors. This includes 8,440 hours for new plan sponsors to program for the ATBT process and all existing Part D organizations for maintenance and updates to the ATBT process (211 organizations x 1 response x 40 hours) and 179 additional hours for new plan sponsors (10 organizations x 17.85 hours x 1 response) for programming to ensure beneficiaries who have made mid-year plan changes are placed in the proper benefit stage reflecting their total annual Part D balances to-date. For processing ATBT transactions, based on the actual number of ATBT transactions in 2012, we estimate 6,596 hours for all plan sponsors (211 x 225,075 x .0001 hours).

Beneficiaries – other insurance information provided at time of enrollment (see January 28, 2005 Part D regulation)	Regulation already accounted for beneficiary burden of submitting other health insurance information at time of enrollment. See PRA 0938-0964.
Pharmacies *39,000chain pharmacies & 17,000 independents. Total – 55,314 * Source – NACDS website 2010)*	This increase is based on 2012-2013 data. We estimate the pharmacist 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 pharmacist an average of 1 minute to query the system and share information with the beneficiary. We estimate the annual burden on the pharmacies is 5,112,800 hours. (56,000 pharmacies x 5,500 responses x .0166 hours = 5,12,800)
States and Secondary payers – • Attestation from states to CMS that they are qualified SPAPs. • Lump sum negotiations *(39 SPAPs)*	This estimate is currently captured under a separate PRA 0938-214 for Medicare Secondary payer purposes and should not have been included as part of the original package. We estimate that the attestation files from the states to CMS will take 78 burden hours to draft and send to CMS. (39 States x 2 hours = 78 burden hours. We estimate that the initial lump sum negotiation process will take each state 60 hours or (2 SPAPs x 60 x 1 response) or 120 burden hours. This reduction is based on program experience that most SPAPs are not using the negotiated lump sum approach with Part D sponsors.

The following collections must be adopted by Part D sponsors, pharmacies and providers of other prescription drug coverage in order to meet the administrative requirements in accordance with 42 CFR 423.464. This section of the regulation requires Part D sponsors to permit State pharmaceutical assistance programs (SPAPs) and other entities providing prescription drug coverage to coordinate benefits with the Part D sponsor.

In accordance with 42 CFR 423.464 of the Federal regulation, Part D sponsors are required to apply protections against high out-of-pocket expenditures by tracking TrOOP expenditures. Under the prior PRA package, PDP Sponsors and MA-PD Organizations were required to accept other payer coverage information from CMS, and collect claims information from the Part D Transaction Facilitator. As CMS' experience with the program grew, we determined that an automated process was necessary to facilitate the transfer of TrOOP-related balances from one plan to another when a beneficiary disenrolls from one plan and re-enrolls in another plan during the plan year. As a result, the automated TrOOP balance transfer process was developed and implemented in 2009.

The Part D organization's collection of information from the Part D Transaction Facilitator for the purpose of coordination of benefits require the following:

- Existing requirement: If new to the program, PDP and MA-PD sponsors will be required to revise their current enrollment and payer systems to receive enrollment information and N1, N2, and N3 transactions from Transaction Facilitator.

- Existing requirement: Programming for Automated TrOOP Balance Transfer (ATBT) will need to be performed by PDP and MA-PDP sponsors that are new to the program. All PDPs and MA-PD sponsors will be required to program systems to implement ATBT process changes.

- All PDP and MA-PD sponsors will be required to receive, respond and process ATBT transactions received from the Part D Transaction Facilitator.

- Existing requirement: PDPs and MA-PDs will continue to enter alternate payer or other health insurance enrollment information into the plans' systems.

To ensure effective coordination of benefits between SPAPs and Part D sponsors, PDPs and MA-PDs may submit bid responses to request for proposals from the States.

- Existing requirement: We continue to estimate that PDPs and MA-PDs will need to develop a bid response to a request for proposal (RFP) from states that wish to adopt the lump sum approach.

Beneficiaries also provide other health insurance information at the time of enrollment (see January 28, 2005 Part D regulation). The burden estimate for this data collection is reflected i**n** PRA package 0938-0964, as required by regulation at 42 CFR 423.32(ii).

When coordinating benefits, pharmacies can utilize an eligibility query system whenever there is a question regarding a beneficiary's Part D or other health insurance coverage. This allows the pharmacy to bill the appropriate plan.

States and Secondary payers are also obligated to perform operations to enhance coordination of benefits under Part D. We continue to require:

- Existing requirement: Submission of Voluntary Data Share Agreements (VDSAs) to CMS. The submission *o*f VDSAs is currently captured as part of the PRA package for the COB contractor. PRA package 0938-0214. The implementing regulations associated with this collection is 42 CFR 489.20(f) & 42 CFR 489.20(g).

- Existing requirement: Submission of monthly enrollment files to COB contractor. The submission of enrollment information is currently captured as part of the PRA package for the COB contractor. PRA package 0938-0214 is 42 CFR 489.20(f) & 42 CFR 489.20(g).

- Existing requirement: Attestations from States to CMS that they are qualified SPAPs.

- Existing requirement: Lump sum negotiations.

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.

The cost of the COB contractor to capture and maintain secondary payer information is already captured under PRA 0938-0214.

15. Changes to Burden

The previous (2010) package included a separate guidance document concerning TrOOP balance transfers. That document can be found in the Medicare Prescription Drug Benefit Manual section 50.8.1 which is included in the 2013 PRA package. The 2010 also included a letter collection form as a supplemental document. That collection is now corrected by adding it to the 2013 package as a form (template) and an instruction (letter). The content of the form has not changed.

This is a revision of an approved collection. Differences in the burden estimates (57,116 respondents (2013) vs 57,227 respondents (2010), 2,492,582 responses (2013) vs 248,018 responses (2010), and 5,205,128 hr (2013) vs 754,788 hr (2010)) are due to a number of factors. CMS implemented several improvements in the processes used to identify claims supplemental to Part D and, thus, significantly increased the number of N transactions created to report these claims payments to Part D plan sponsors. Therefore, plan sponsors receive and process a higher number of these transactions than were previously estimated.

Additionally, 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 increase the number of transactions occurring in the month immediately following the enrollment change and to incorporate three series of end-of-year transactions for all

beneficiaries who changed plans during the contract year. This resulted in an increase in the overall volume of ATBT transactions from our previous estimates.

The implementation of enhancements to the eligibility query, including the addition of several new fields in the query response has improved the utility of the transaction for pharmacies and created an increase in the overall number of queries. Therefore, based on our current experience, the previous burden estimates associated with these queries was understated.

16. Publication/Tabulation Date

CMS requests that the information be submitted per the current version of Chapter 14 – Coordination of Benefits (Medicare Prescription Drug Benefit Manual), released on September 26, 2008.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

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.