Supporting Statement for Collecting Benefit Coordination Data

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 TrOOP facilitator.

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, via the TrOOP facilitation contractor, automated the transfer of beneficiary coverage information when a beneficiary changes Part D plans during the plan year. We refer to this action as the Automatic TrOOP Balance Transfer (ATBT). When a beneficiary switches plans during the plan year, the TrOOP facilitation contractor transfers the beneficiary's TrOOP balance information to the enrolling plan. This improved technology is in lieu of the disenrolling plan manually submitting this information to the enrolling plan.

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 National Council for Prescription Drug Programs (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 query of the TrOOP facilitator when a Part D beneficiary presents him/herself at the pharmacy without a card save pharmacies time. Prior to the TrOOP facilitator 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 TrOOP facilitator query process assists the pharmacist when a beneficiary does not know what other health insurance coverage they have 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 private insurers.

6. Less Frequent Collection

Failure of the Part D sponsors, States and other payers to submit this 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 the CMS' process for tracking and reporting true out-of-pocket 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:

A 60-day Federal Register notice published on May 18, 2010. 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 contract between payers, primary or secondary in order to procure the true out-of-pocket expenditures of a Part D beneficiary.

On May 11, 2005, CMS awarded a contract to NDC Health (now Relay Health) to act as the TrOOP Facilitation Contractor. The TrOOP Facilitation Contractor is responsible for establishing procedures for facilitating 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 Relay Health to provide TrOOP facilitation. Beginning in 2009, the TrOOP Facilitation Contractor will provide the transfer of coverage 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 claims transaction standards with the industry given the implementation of the new Medicare prescription drug benefit. CMS has been in constant consultation with industry experts via the 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

248,018 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 information from TrOOP Facilitator (N1, N2, N3 transaction). • Lump sum payments • Automatic TrOOP Balance Transfer	The Part D organization's collection of supplemental payer information from the beneficiary and TrOOP facilitator for the purposes of calculating TrOOP will require: • Revisions to their current enrollment and payer systems – Systems must receive enrollment information and N1, N2, and N3 transactions from TrOOP 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). Large reduction is based upon fewer new organizations (reduction in respondents) entering into Part D contracts than at the beginning of the program. • Revised the estimate for processing claims through TrOOP facilitator based upon actual TrOOP facilitator data for CYs 2007-2008. The annual estimate was recalculated using actual number of responses for all Part D organizations. 196 organizations x 191,377 responses per respondent x .000139 = 5210 burden hours. Entering alternate 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 3hoursfor all Part D organizations. Lump sum approach – PDPs and MA-PDs will need to develop a bid response to an RFP from states that wish to adopt the lump sum approach. We estimate that an initial 60 hours per sponsor will be dedicated to this process or (60 hours x 196 orgs x 1 response.)**11,760** hours for all plan sponsors. The reduction in respondents is due to reduction in the number of organizations subject to this requirement. • Automatic TrOOP Balance Transfer (ATBT): Systems programming and maintenance for ATBT. We estimate that 7840 hours for all plan sponsors (196 orgs. x 1 x 40 hours) to program for the transfer and 1520 hours for all plan sponsors (196 x 55,855 x 0001) to process/update transactions. • Additional programming for ATBT process to ensure beneficiaries are placed in the proper benefit stage reflecting their total Part D annual utilization to date despite midyear plan switching. We estimate that for all plan sponsors (196 orgs. x 1 response x 17.85 hours) the programming will result in 3,499 hours for all plan sponsors.

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)*	We estimate the pharmacist may need to query the troop facilitator system an average of 12 times per month, with the initial months averaging more occurrences than latter months. 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 hours on the pharmacies is 724,158. (56,000 pharmacies x 779 responses x .0166 hours =724,158)
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 0938-0214 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 TrOOP Facilitator. As CMS' experience with the program grew, we discovered that this process lacked an automatic way to transfer the TrOOP balance from one plan to another when a beneficiary disenrolls from one plan and re-enrolls in another plan during the plan year. Therefore, as the program evolved, CMS determined that improvements in this system were necessary. Therefore, the automatic TrOOP balance transfer process was developed.

The Part D organization's collection of information from the TrOOP facilitator for the purpose of coordination 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 TrOOP Facilitator.

- Additional requirement : Programming for the Automatic TrOOP Balance Transfer (ATBT) will need to be performed for all PDP and MA-PDP sponsors. PDPs and MA-PD sponsors will be required to program systems to receive and transfer ATBT transaction to the TrOOP Facilitation Contractor.

- In addition to the exchanges and updates noted above, exchanges and updates for ATBT. PDP and MA-PD sponsors will be required to receive and transfer ATBT transactions. This is in lieu of a manual process.

- Exisitng 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 TrOOP facilitator contract –

- Receives and maintains eligibility data
- Supports query from pharmacy regarding eligibility, include in message on the E1 segment of the NCPDP v. 5.1
- Captures primary response and secondary payer claim submission,
- Routes N1 transaction to Part D plans (TrOOP costs)
- Provide CMS with copies of the N1 transactions (at least in batch).

The estimated cost of the TrOOP 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

This is a revision of a currently approved collection. The difference in burden estimate is based upon an overstated estimate at the beginning of the Part D program associated with the processing of secondary claims through the TrOOP facilitator. Since the TrOOP facilitator was a new CMS function in 2006, CMS had no historical data to use to calculate a reasonable estimate. Furthermore, it was difficult to estimate the impact with any specificity the burden associated with the new Part D coordination of benefits requirements at the point-of-sale for pharmacies, prescription drug plan sponsors and states. This due to the functions being new to the agency and the lack of familiarity with the automation of the COB functions at the pharmacy. CMS now has data directly from the TrOOP facilitator and the plans to support an estimate that more closely aligns with the actual burden associated with these requirements.

We also found that the burden associated with the submission of OHI by other payers is already accounted for the OMG package 0938-0214 as this information is already collected for Medicare Secondary Payer purposes.
Additionally, CMS, via the TrOOP facilitation contractor, will automate the transfer of beneficiary coverage information when a beneficiary changes plans. When a beneficiary switches plans during the plan year, the TrOOP facilitation contractor will transfer the

beneficiary's TrOOP balance information to the enrolling plan. In lieu of a manual transfer of this information, plans will send and accept the transfers from the TrOOP facilitator contractor.

CMS is also adding a new requirement as part of the ATBT process to (1) calculate and maintain monthly TrOOP and Total Drug Spend benefit accumulator totals for each part D beneficiary, (2) to transmit those monthly values whenever they receive electronic inquiry transactions from the CMS TrOOP Facilitator, (3) to receive electronic update transactions containing accumulator values from previous plans on their new enrollees, and (4) adjust their enrollees' TrOOP and Total Drug Spend benefit accumulators to reflect utilization in previous Part D plans. This requirement automates the process of ensuring beneficiaries are placed in the proper benefit stage reflecting their total Part D annual utilization to date despite midyear plan switching.

16. Publication/Tabulation Date

CMS requests that the information be submitted per the recent 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 not exceptions to the certification statement.