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 will require some improved information technology. CMS, via the TrOOP facilitation contractor, will automate the transfer of beneficiary coverage information when a beneficiary changes plans. 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 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 will 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 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 February 27, 2009. 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

2,153,767,270 is the total number of responses submitted for approval and 1,017,914 is the total burden hours. Total Salary is ($26.92 * 1,017,914) =$27,402,245

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 *[Estimate - 370 Part D organizations * Source Medicare Drug Benefit Group – Teresa DeCaro.]* *[Estimate of individuals with other health insurance* Source TrOOP Facilitation SOW]* *[Estimate of annual scripts filled – 12/mo (based on Kaiser FF Analyses of Price and utilization data) 12 + 12 months for 144 annual fills]* **TOTAL HOURS: 883,190** **TOTAL RESPONSES: 2,145,800,740**	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 370 organizations for an annual estimated burden of (60 hours x 370 orgs.) or **22,200 hours** for all plans. (370 orgs. x 1 response = 370 responses) • We estimate at a maximum that each Part D organization will have approximately 60% of their enrollees (total estimated enrollees = 66,666) enrolled in secondary coverage or 40,000, with an average annual prescription fill of 144 prescriptions per beneficiary. Each organization will have 40,000 individuals filing 144 claims annually. Processing these transactions through the TrOOP facilitator will take 1 second per claim or 5.76 million seconds (or 1600 hours) for each Part D organization or (1600 hours x 370 organizations) **592,000 hours** total for all Part D organizations. Responses: (370 orgs. x 40,000 individuals x 144 claims responses = 2.131 billion responses) • Entering alternate payer or other health insurance enrollment information into the plans' systems. Estimate each plan will have 40,000 beneficiaries with secondary coverage. Manually entering the enrollment information from the applications will take approximately 1 minute per application for a total of 40,000 minutes (667 hours) per Part D organization or (370 orgs. x 667 hours) **246,790 hours** for all Part D organizations (370 org. x 40,000 individuals responding = 14.8M responses) • 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 am initial 60 hours will be dedicated to this process or (60 hours x 370 orgs.)**22,200 hours** for all plans. (370 orgs. x 1 response = 370 responses)
Beneficiaries – other insurance information provided at time of enrollment (see January 28,	Regulation already accounted for beneficiary burden of submitting other health insurance information at time of enrollment.

2005 Part D regulation)	
Pharmacies *(37,444 chain pharmacies & 17,870 independents. Total – 55,314 * Source – NACDS 2004 data)* **TOTAL HOURS: 132,753 hours** **TOTAL RESPONSES: 7,965,216 responses**	. 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 burden on the pharmacy on a monthly basis will be 12 minutes total – higher in the early months of implementation compared with later in the plan year. Total annual burden is 144 minutes (or 2.4 hours) per pharmacy per year or (2.4 hours x 55,314 pharmacies) **132,753 hours** for all pharmacies. (55,314 pharmacies x 12 queries x 12 months =7,965,216 responses)
States and Secondary payers – • Submission of Voluntary Data Share Agreements to CMS, • Submission of monthly enrollment files to COB contractor, • Updates and corrections to these files, • Attestation from states to CMS that they are qualified SPAPs. • Lump sum negotiations *(21 SPAPs and 615 secondary payers (employers, PBMs, Insurers)* **TOTAL HOURS: 1,971 hours** **RESPONSES: 1,314 responses**	We estimate that the burden to submit VDSAs to CMS will take 30 minutes per payer to complete and forward to CMS. Annual estimate per organization is 30 minutes or (.5 hours x 636) **318 hours**. (636 respondents) We estimate that the burden for payers to submit monthly data feeds, updates, and corrections to the COB system contractor will take 3 minutes per state. This will occur monthly. Annual estimate per payer is 36 minutes or (.6 hours x 636) **382 hours** for all payers to submit monthly data feeds. (636 secondary payers x 1 response = 636 responses) We estimate that the attestation files from the states to CMS will take the states 30 minutes to draft and send to CMSO. SPAPs currently operating (21 X 30 = 630 minutes) or **10.5 hours** total burden for all states. (21 x 1 response = 21 responses) We estimate that the initial lump sum negotiation process will take each state 60 hours or (21 SPAPs x 60) or **1,260 hours** for all states annually. (21 x 1 = 21 responses)

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 purposes 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.
- In addition to the programming noted above, 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.
- Existing requirement: We estimate at a maximum that each Part D organization will receive approximately 154,738 claims annually through the TrOOP facilitator.

- 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 continues to require that PDPs and MA-PDs to voluntarily 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.

- Existing requirement: The total annual number of eligibility queries (responses) from 10/27/2007 through 10/26/2008 was 66,067,290. Based upon the total number of pharmacies for 2007 (55,855), the average number of queries per pharmacy increased. . To reiterate, this is an *offset* to a manual process of the pharmacy calling the plan directly.

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 of 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.
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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. While there is no change to the burden reported at this time, the revisions reflect the changes to the new Automatic TrOOP Balance Transfer process.

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.

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.