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CENTER FOR BENEFICIARY CHOICES

DATE December 15, 2006

Memorandum to: All Part D Sponsors

Subject: Release of the Final Prescription Drug Benefit Manual Chapter 14 – Coordination of Benefits

From: Cynthia Tudor, Ph.D., Director, Medicare Drug Benefit Group

CMS is pleased to release the final chapter for the Prescription Drug Benefit Manual regarding coordination of benefits (COB). CMS considered each of the comments we received on the draft COB Guidance initially released on June 22, 2006. This chapter provides clarifications to 2005 policy guidance, describes updated systems and processes related to COB, and explains new COB policy and requirements for 2007. In addition to these changes, this chapter includes new appendices that contain a model COB survey and address the applicability of the Part D COB requirements to PACE organizations. If you have any questions regarding this chapter please contact Deborah Larwood at (410) 786-9500 or deborah.larwood@cms.hhs.gov or Christine Hinds at (410) 786-4578 or christine.hinds@cms.hhs.gov.

Medicare Prescription Drug Benefit Manual

Chapter 14 – Coordination of Benefits

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10 – Introduction

This chapter provides guidance to Part D sponsors regarding our requirements and procedures for coordination of benefits (COB) with other providers of prescription drug coverage. The chapter is divided into five main areas:

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- Section 50 – Part D Plan Requirements
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20 – Overview

Part D sponsors are required to coordinate with State Pharmaceutical Assistance Programs (SPAPs) and other providers of prescription drug coverage with respect to the payment of premiums and coverage, as well as coverage supplementing the benefits available under Part D.[*] The Medicare Modernization Act (MMA) specified that these coordination requirements must relate to the following elements: (1) enrollment file sharing; (2) claims processing and payment; (3) claims reconciliation reports; (4) application of the protection against high out-of-pocket expenditures by tracking true out-of-pocket (TrOOP) expenditures; and (5) other processes that CMS determines.

When a Medicare Part D enrollee has other prescription drug coverage, COB allows the plans that provide coverage for this same beneficiary to determine each of their payment responsibilities. This process is necessary in order to avoid duplication of payment and to prevent Medicare from paying primary when it is the secondary payer. While this is the principal purpose of COB within the contexts of Medicare Parts A and B, COB also serves an additional function within the Part D context: it provides the mechanism for support of the tracking and calculating of beneficiaries' "true out-of-pocket" (TrOOP) expenditures, or "incurred costs" as defined in the MMA and our implementing regulations. Costs for covered Part D drugs are treated as "incurred" only if they were paid by the individual (or by another person, such as a family member, on behalf of the individual), paid by CMS on behalf of a low-income subsidy-eligible individual, or paid under a qualified SPAP as defined in our regulations. Costs do not count as "incurred" when: 1) no benefits are provided because of the application of either a formulary or the Medicare Secondary Payer (MSP) laws, or 2) when costs are reimbursed through insurance or otherwise, a group health plan, or similar third party arrangement. Therefore, only certain costs not paid for by the Part D plan count toward TrOOP. In 2007, under the defined standard Part D benefit, catastrophic coverage is triggered only after $3,850 of TrOOP expenditures.

The MMA provided us with authority to impose user fees to defray the costs of Part D COB activities, as well as to retain a portion of those user fees to offset costs associated with the TrOOP facilitation process. The MMA prohibits our levying of user fees on SPAPs, however. In our regulations, we clarify that only Part D plans – not SPAPs or other payers –

[*] Under 42 CFR 423.458(d), Part D requirements may be waived for Programs of All-Inclusive Care for the Elderly (PACE) organizations if the requirements are determined to be duplicative of, or in conflict with, provisions that would otherwise be applicable to these organizations. Appendix D provides additional guidance on the applicability of the COB requirements to PACE organizations.

will be assessed user fees beginning in 2006. However, we also note that, while Part D sponsors may charge user fees to other payers for COB activities, these user fees must be reasonable and related to the Part D sponsors' actual costs of COB with these entities. In addition, any user fees Part D plans charge other entities must specifically exclude those activities which are covered by the user fees CMS is collecting for COB. Thus, for example, Part D plans may not charge user fees for activities such as the costs of the claims transaction by supplemental payers (since Part D user fees funded by CMS are used in part for that purpose), but they could charge for activities such as the exchange of claims data.

Although this chapter provides guidance primarily for Part D plans, the various processes associated with COB involve interaction between multiple parties. For that reason, we provide below detailed guidance regarding the COB requirements applicable to those various parties including beneficiaries, Part D plans, and other payers.

In Appendix A of this guidance, we provide an illustration of how the TrOOP facilitation process works. In Appendix B, we offer a sample format for the beneficiary COB survey, and in Appendix C, we provide detail on specific issues that may relate to (or be of particular interest to) other payers and entities with which Part D plans, per the requirements of 42 CFR 423.464(f), are required to coordinate, including SPAPs, Medicaid, VA, TRICARE, Indian Health Service and tribal health coverage, safety-net providers, patient assistance programs (PAPs), personal health savings vehicles, AIDS drug assistance programs (ADAPs), PACE plans, and Medicare Part B. Further guidance on systems requirements and technical details involved in the COB process has been issued in other communications and is included here by reference. In Appendix D, we address applicability of COB to PACE requirements.

30 – CMS Requirements

CMS leveraged its existing Medicare COB processes to facilitate COB under Part D. In addition, through the use of a TrOOP facilitation process that uses an existing industry claims transactions set (described in further detail in Section 30.4 of this chapter), we support the tracking and calculation of enrollees' TrOOP balances by Part D plans.

30.1 – Enrollment File Sharing

Except for employers/union plans that are required by Medicare Secondary Payer-related law to report enrollment information on certain active employees, there is no requirement for other payers of drug benefits to report their enrollment to CMS or the plans. The COB enrollment file sharing programs provide sufficient inherent incentives for other payers to coordinate drug benefits, however. Other payers voluntarily provide information regarding prescription drug coverage they offer that is either primary or supplemental to Part D.

CMS coordinates benefits with other payers with respect to Part A and B coverage to reduce mistaken payments and administrative expenses that would otherwise be incurred by the Medicare program. Currently, CMS uses its COB Contractor to collect information on beneficiaries' other coverage primarily through the use of data sharing agreements. The Voluntary Data Sharing Agreements (VDSAs) and Coordination of Benefits Agreements (COBAs) that already existed were modified to include Part D information. CMS also created new types of agreements (such as those with SPAPs) specifically for the exchange of Part D

information. After an agreement is executed, the other payer sends the COB Contractor a file of its enrollees. For Part D purposes, the COB Contractor: 1) compares the list of the other payer's enrollees to the current population of Medicare Part D enrollees; 2) captures and maintains the resulting matches and any information updates; and 3) transmits the matches/updates to the CMS Medicare Beneficiary Database (MBD). CMS sends this information to the TrOOP facilitator and the plan.

COB files from CMS consist of a detail record for each enrollee whose other payer information is reported in the attachments to the detail record. Attachments to the detail record may include up to 20 primary records containing information on other payers that are primary to Part D, and up to 20 supplemental records containing information on payers that pay after Part D. The data elements that are included, if applicable, in the detail, primary and supplemental records are reflected in tables below.

Table 30.1-1 COB File—Data Elements in Detail Record

Record Type
HICN/RRB Number
SSN
Date of Birth
Gender Code
Contract Number
Plan Benefit package
Action Type

Table 30.1-2 COB File—Data Elements in Primary Record

Record Type
HICN/RRB Number
SSN
Date of Birth
Gender Code
RxID Number
RxGroup Number
RxBIN Number
RxPCN Number
Rx Plan Toll Free Number
Sequence Number
COB Source Code
MSP Reason (Entitlement Reason from COB)
Coverage Code
Insurer's Name
Insurer's Address-1
Insurer's Address-2
Insurer's City
Insurer's State
Insurer's Zip Code
Insurer TIN
Individual Policy Number
Group Policy Number
Effective Date
Termination Date
Relationship Code
Payor ID
Person Code
Payer Order
Policy Holder's First Name
Policy Holder's Last Name
Policy Holder's SSN
Employee Information Code
Employer's Name
Employer's Address 1
Employer's Address 2
Employer's City
Employer's State
Employer's Zip Code
Filler
Employer TIN
Filler
Claim Diagnosis Code 1
Claim Diagnosis Code 2
Claim Diagnosis Code 3
Claim Diagnosis Code 4
Claim Diagnosis Code 5
Attorney's Name
Attorney's Address 1
Attorney's Address 2
Attorney's City
Attorney's State
Attorney's Zip
Lead Contractor
Class Action Type
Administrator Name
Administrator Address 1
Administrator Address 2
Administrator City
Administrator State
Administrator Zip
WCSA Amount
WCSA Indicator

Table 30.1-2 COB File—Data Elements in Supplemental Record

Record Type
HICN/RRB Number
SSN
Date of Birth
Gender Code 1 33 … 33 CHAR 0=unknown, 1 = male, 2 = female
RxID Number
RxGroup Number
RxBIN Number
RxPCN Number
Rx Plan Toll Free Number
Sequence Number
COB Source Code
Supplemental Type Code
Coverage Code
Insurer's Name
Insurer's Address-1
Insurer's Address-2
Insurer's City
Insurer's State
Insurer's Zip Code
Individual Policy Number
Group Policy Number
Effective Date
Termination Date
Relationship Code
Payor ID
Person Code
Payer Order

Further information about the format and business rules of the COB file to plans is contained in Section 10 of the Plan Communications User's Guide (PCUG). The guide is available on the website at http://www.cms.hhs.gov/MedicareMangCareSys/Downloads/PCUGv1.1%20(11.07.05).pdf. For more information about current Medicare COB processes, see the Part D COB website currently available at http://www.cms.hhs. gov/COBGeneralInformation/.

The COB Contractor will send as much information as is available. In some cases, CMS through the COB Contractor may determine there is other prescription drug coverage, but may be unable to identify the Rx identifiers. In such cases, CMS will supply the information so that the plans are at least aware of the other coverage.

30.2 – Validation of Information about Other Payers

When a Part D plan or a beneficiary provides information to the COB Contractor about other coverage, the COB Contractor validates the completeness of this information, then applies and maintains it in MBD. MBD transmits this information to both the TrOOP Facilitator and Part D plans from the MARx system via the COB file.

The COB Contractor's role in Part D COB is to assist plans in identifying other coverage and in determining whether other payments count towards the beneficiary's TrOOP by specifying the supplemental payer type.

The table below crosswalks the TrOOP eligibility of payments by other payers with the Medicare secondary payer (MSP) reason codes and insurance or coverage type codes on the COB file.

Table 30.2-1 Other Payer Codes and TrOOP Eligibility

Other Payer	MSP Reason Code	Insurance or Coverage Type Code	Relationship of Coverage to Medicare	TrOOP Eligibility
Employer Group Health Plan	A (Working Aged) B (ESRD) G (Disabled)		Primary	N
Non-Employer Group Health Plan	C (PPO) D (Auto insurance; no fault) E (Workers' Compensation) F (Liability) H (Black Lung)		Primary	N
Secondary Insurance		L (Supplemental insurance) M (Medigap) O (Other)	Secondary	N
Federal Government Programs		T (Federal Employees Health Benefit Program [FEHBP], Veterans Administration coverage; Indian Health Service/Tribal coverage**) 2 (TRICARE)	Secondary	N

Other Payer	MSP Reason Code	Insurance or Coverage Type Code	Relationship of Coverage to Medicare	TrOOP Eligibility
Qualified SPAP*		Q	Secondary	Y
Non-qualified SPAP		N	Secondary	N
Medicaid		1	Secondary	N
PAPs		P	Secondary	N
ADAPs		S	Secondary	N
Charities		R	Secondary	Y
Health Reimbursement Accounts ***		Z	Secondary	N

* State-only funded SPAPs
** Tribes using Tribal-only money qualify as TrOOP-eligible, but manual processing will be necessary to handle these cases.
*** For non-working, aged beneficiaries, payments are secondary to Medicare and non-TrOOP-eligible.

30.3 – Establishing the Order of Payment for Part D Coordination of Benefits

In order to provide a consistent set of rules for the order of payment on Part D claims and establish a basis for the accurate calculation of the TrOOP balance, CMS establishes that Part D plans and all secondary payers on Part D claims should adhere to the following order of payment standards. All payers are legally required to adhere to MSP laws and any other federal and state laws establishing payers of last resort (e.g., TRICARE). In all other situations, the Rules for Coordination of Benefits adopted in the most current National Association of Insurance Commissioners Coordination of Benefits Model Regulation should be followed.

The COB Contractor includes payment order indicators on other payer records it sends to MBD. Plans use this data element to sort COB records for display in reply transactions to the pharmacy. The COB Contractor calculates payer order based on MSP rules, relationship to policyholder, and type of supplemental insurance. Rules for using the payment order indicator are contained in the PCUG.

30.4 – Contracting with a TrOOP Facilitation Contractor

All Part D Plans must correctly calculate the TrOOP amount in order to properly adjudicate beneficiary claims, as well as to communicate this information to plan enrollees. This process is logistically complex because there may be multiple payers (for example, SPAPs or employer or union plans). True COB, in which the order of payment among multiple payers

with responsibility for paying prescription drug claims on behalf of an individual is established and programmed into the systems of the secondary payers, did not generally take place in pharmacy benefit management prior to Part D implementation. In lieu of Part D plans separately setting up procedures to coordinate benefits with every other payer with responsibility for drug coverage for one of their Part D enrollees, CMS published a request for comment on the feasibility of an online real-time process. In response to this CMS request, representatives from pharmacies, pharmacy benefit management (PBM) companies and pharmacy data processing and standard-setting organizations provided extensive input and comments to design an automated solution for COB and the facilitation of the TrOOP accounting process. The industry, working in collaboration with the National Council of Prescription Drug Programs (NCPDP), developed a TrOOP facilitation process that allows the majority of pharmacy claims processing to take place "real time" at the pharmacy at point of sale (POS). To this end, supplemental payers are required to utilize the HIPAA coordination of benefits transaction standard, which requires the use of the NCPDP Telecommunication Standard Implementation Guide to communicate secondary payer transactions back to the primary Part D plan for purposes of tracking TrOOP in real time. Version C.1 of the NCPDP Implementation Guide first detailed the processing requirements involved in the TrOOP facilitation process.

In 2005, CMS awarded a contract to Per Se Technologies (previously NDC Health) to act as the TrOOP Facilitation Contractor (also referred to as the TrOOP Facilitator) for Part D claims processing. The TrOOP Facilitation Contractor, in conjunction with CMS, is responsible for establishing procedures for facilitating eligibility queries (E1 transactions) at POS, identifying costs that are being reimbursed by other payers, and for alerting Part D plans about such transactions.

30.4.1 –TrOOP Facilitation Process

With the implementation of Medicare Part D, new electronic transaction capabilities became available to pharmacies. These offer pharmacies the ability to submit E1 transactions without the need to fill a prescription and to bill payers supplemental to Medicare. A pharmacy uses an E1 transaction to submit real-time transactions to the TrOOP Facilitator. Eligibility transactions are used to determine a Medicare beneficiary's Part D coverage information.

Pharmacies use this service when the beneficiary does not have their Medicare Part D Plan Card information to retrieve information needed to bill a claim to a patient's insurance plan, or to determine billing order if the beneficiary has multiple insurance coverage.

Part D Plans, supplemental payers, switches (claims routers), and the TrOOP Facilitator must interact to accurately track a patient's true out of pocket expenses. Claims to supplemental payers, known as B transactions, are submitted by the pharmacy to their switch. The switch will forward to the TrOOP Facilitator the B transactions that are not rejected by the supplemental payer and that contain a RxBIN/PCN combination for a plan that covers Medicare Part D beneficiaries. This RxBIN/PCN combination is the flag that switches use to route the data to the Facilitator.

The TrOOP Facilitator uses the B transaction to trigger the creation of a Reporting Transaction (N transaction) Request and delivers the Request to the Part D Plan in real-time.

All supplemental billing claims must be processed through a switch so that the switch can deliver the transactions to the TrOOP Facilitator in order for accurate TrOOP reporting at the Part D Plan.

30.4.2 –Enhancements to E1 Transactions

Prior to the implementation of Part D in 2006, additional functionality for eligibility inquiries was made available through an expanded E1 transaction. This enhanced E1 capability enables pharmacies to separately request verification of a beneficiary's Medicare Part A/B eligibility— an essential step in the POS facilitated enrollment process (described in Section 50.15. Payment Reconciliation of this chapter).

As of December 1, 2006, further enhancements to the E1 inquiry added data elements to the E1 response. Expanding the E1 response to include, for example, the Part D plan's contract number, benefit ID, benefit effective date and benefit termination date, will better inform pharmacies of beneficiaries' enrollment in Part D.

30.4.3 –Real-time versus Batch Processing

For instances in which Part D plan enrollees' secondary coverage is identified in advance by CMS systems (as described in Section 30.1 of this chapter), multiple-payer claims are automatically adjudicated at the POS. The TrOOP Facilitation Contractor captures secondary payer claims transactions based on unique routing information collected previously at enrollment or through the COB Contractor's system. The TrOOP Facilitation Contractor also has a batch process available for claims that it receives in a manner other than real time (for example, claims from programs such as the Indian Health Service (IHS) or those presented by the beneficiary to a secondary payer in hard copy). Other payers can then send their paid claims data directly to the TrOOP Facilitation Contractor in batch form. Once the contractor receives the batched paid claims data, it will follow the same online process, creating an NCPDP N1 transaction and sending it to the beneficiary's Part D plan for accurate TrOOP recalculation.

30.4.4 –Enhancements to N1 Transactions

CMS, through the TrOOP Facilitation Contractor, is seeking to enhance N1 transactions. The enhancements would create processes for re-generating N transactions. One enhancement, for example, would involve an analysis of N transactions that were previously generated by the TrOOP Facilitator, but were rejected by the Part D plan to identify additional criteria for determining when a re-generation of the N transactions to the plan would be appropriate.

Another enhancement would allow the TrOOP Facilitator to retry N transactions that were initially delayed because the Part D plan was not in the Eligibility Index when the supplemental were were originally received by the TrOOP Facilitator.. As soon as possible in 2007, CMS and the TrOOP Facilitation Contractor will provide guidance on these enhancements.

30.4.5 –TrOOP Accounting

Part D plans should note information about a payer's TrOOP eligibility status based on the information in the COB file in order to determine whether a payment should count toward TrOOP or not. We recognize that pharmacies play an integral role in claims processing and TrOOP accounting, and CMS has engaged pharmacists in extensive outreach efforts so that they fully understand how they can interact with these systems. For more detail about the TrOOP facilitation process, please see Appendix A.

30.5 –Assessment of COB User Fees

The MMA provided CMS with the authority to impose user fees to facilitate the transfer of information necessary for benefit coordination. In conjunction with this authority, CMS is using the fees for activities such as, covering the cost of N1 transactions, funding the COB Contractor, and supporting CMS systems upgrades for transferring COB data to plans.

Sufficient time has elapsed since the implementation of Medicare Part D for CMS to refine our budgetary needs related to the information transfer necessary for coordination of benefits (COB) in Part D. Over these past months, we have made a number of systems improvements, such as enhancing the eligibility query (E1) response, and have increased systems security for the COB-associated data exchanges.

Further systems upgrades are planned or under discussion for next year. In addition to automating the transfer of TrOOP balances between plans when beneficiaries transfer between plans during the coverage year, we are exploring an expanded role for the TrOOP Facilitator to further support Part D Plan activities related to COB. Examples of these enhancements include:

- Replaying N transactions when a claim initially rejects;
- Development and production of reports to Part D plans on N1s; and
- Analysis and creation of a test environment to improve the E1 match rate.

As a result, the user fee will increase for 2007 to $1.32 per enrollee. It will collected at the rate of $0.15 per enrollee per month from January through August, and $0.16 per enrollee for the month of September.

40 – Beneficiary Requirements

40.1 – Providing Information to Plans on Other Coverage

Beneficiaries must supply Part D plans with information about other prescription drug coverage they have. As provided in the MMA, beneficiaries are legally obligated to report this information, and any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from Part D. How CMS will determine what constitutes "material misrepresentation" will be explained in future guidance to plans on various enrollment issues. Part D plans must regularly survey their enrollees regarding any other coverage they may have (as described in section 50.2 of this chapter) and report that information to the COB Contractor for validation.

40.2 – Using On-line Processing

CMS expects beneficiaries to take advantage of automated real-time prescription drug claim processing whenever it is available so that the supplemental payer information can be utilized to coordinate benefits seamlessly at the point of sale. Paper claim (receipt) submission should be limited to those situations (such as out-of-network pharmacies) in which on-line claims processing is not available at the pharmacy in order to promote accurate TrOOP accounting, and to minimize both administrative costs to the Part D plans and the Medicare program as well as opportunities for fraudulent duplicative claim reimbursements.

40.3 – Submitting Documentation for Off-line Processing in a Timely Basis

Beneficiaries are responsible for submitting documentation for purchases that are made off-line (i.e., when on-line claims processing is not available at the pharmacy). These would include out-of-network claims, claims resulting from the use of drug discount cards other than that of the beneficiary's Part D plan, as well as other occasions on which the beneficiary had to pay and submit a paper claim to the plan. It is the beneficiary's responsibility to submit documentation in accordance with reasonable timeframes and procedures established by the plan, for instance plans may require the use of specific forms, so that beneficiary TrOOP balance and other accumulators can be updated timely.

Given CMS requirements for Part D plan submission of prescription drug event (PDE) data at the end of the coverage year, plans may need to limit the length of time they can afford beneficiaries at the end of the year for submitting documentation of off-line claims to ensure these claims data are available for the payment reconciliation process. While CMS allows plans a three-month window at the end of the coverage year for submission of claims related to that year, beneficiaries should not delay in submitting this documentation.

50 – Part D Plan Requirements

50.1 – Providing 4Rx Data on Primary Coverage

Currently, plans submit enrollments to the Medicare Advantage – Prescription Drug (MARx) system. When MARx accepts an enrollment and transmits a successful reply to plans, plans are required to follow up with a 4Rx data transaction. The 4 Rx data, including the RxBIN, Processor Control Number (PCN), Group ID and Cardholder ID, are identifying data required for claims routing and are submitted by plans to the Medicare Beneficiary Database (MBD). If MBD accepts these 4Rx data, the data are then sent to the TrOOP facilitation contractor to support eligibility (E1) transactions from pharmacies, which are needed anytime a beneficiary shows up for the first time at a pharmacy and does not have a plan-issued card for drug benefits. While plans have worked with us to reduce the time between enrollment and complete 4Rx information, the time lag between enrollment transactions and 4Rx submissions can be 7-10 days.

In 2007, in order to better facilitate access at point of sale, CMS expects to significantly reduce this time lag by revising the enrollment transaction process to require 4Rx data on every enrollment transaction received from plans. Two important benefits will be derived from this process change. CMS and the TrOOP Facilitation Contractor will have a set of 4Rx data for all enrollees whose transactions have been processed successfully in CMS systems. Most of the time lag between CMS accepting an enrollment and the TrOOP Facilitation Contractor having 4Rx data will be eliminated.

We expect to implement this process as early as possible in 2007. Plans may need to make programming and business process changes to expedite enrollment in PBM systems and allow more frequent processing of CMS transactions.

50.2 – Surveying Beneficiaries regarding Other Prescription Drug Coverage and Transmitting Such Information to CMS

As provided in the MMA, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that they have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. Part D plans must, therefore, regularly survey their enrollees regarding any other prescription drug coverage they may have and report that information – including, if known, any Rx identifiers (RxBIN, PCN, RxGRP, and RxID) – to the COB Contractor so that it can be validated, captured, and maintained in MBD for COB purposes. Anytime a Part D plan receives information concerning a change, this information should be sent electronically to the COB Contractor within 30 days of receipt. Plans shall not transmit information about other coverage that the COB Contractor has already applied to MBD and that the plan has already received in the COB file, but rather only change transactions.

Except as noted, this survey should be performed within thirty (30) days of the date the Plan processes a beneficiary's enrollment and annually thereafter. Beneficiaries who may be exempted from the survey at the time of Plan enrollment include auto-enrolled beneficiaries, those who are deemed to have elected an MA-PD, and those individuals who are passively enrolled in a MA-PD Special Needs Plan. Plans, however, must survey these individuals, along with all other Plan enrollees, as part of their annual survey process. In addition to the exempted beneficiaries, if an enrollee indicates on his or her enrollment form that there is no other prescription drug coverage, no plan follow-up is required until the annual survey is performed. However, if the enrollee indicates on the enrollment form that he or she in fact has other prescription drug coverage or does not provide any response to those questions, the plan must perform the 30-day survey.

The survey should collect from the enrollee the same information on other payers that Part D plans must submit electronically to the COB Contractor. Plans have the flexibility to design their survey process according to their own needs. CMS has developed an electronic survey form (see Appendix B) that plans are free to use or adapt for this purpose. Please note that use of this form is optional and plans are not required to submit their surveys for marketing material review. Plans may conduct their survey by telephone, mail or in-person. Further, if the Plan wishes to do so, this survey may be combined with the working aged survey for MA

plans. If the Plan elects this approach, the timing of the combined survey must be such that the information is received by the COB Contractor by September 1 in order for the appropriate payment adjustments to be made based on the working aged information provided by the beneficiaries.

A non-response to the survey regarding other prescription drug coverage cannot be interpreted as a negative answer, since effective coordination of benefits with other prescription drug coverage requires that plans be aware of any other prescription drug coverage a beneficiary may have. Therefore, plans are required to follow up with enrollees who fail to respond. Follow-up with non-responding enrollees may be conducted by telephone, mail or in person. After unsuccessful attempts to gain a response using one mode, plans may find a change to another mode is more productive. Also, if the beneficiary has had drug claims, plans may contact the pharmacy to determine if COB information was captured while the beneficiary was in the pharmacy. Plans are expected to make multiple attempts to follow up with non-responding enrollees using multiple methods to secure beneficiary responses. CMS will examine this issue of beneficiary survey follow-up and provide further guidance for 2008.

Part D plans also are responsible for sending electronic updates about their enrollees' other sources of prescription drug coverage to the COB Contractor. Since supplemental payer information is essential for coordination of benefits, plans should submit this information to the COB Contractor at least monthly.

50.3 – Connecting to Systems Supporting COB

Data from CMS to plans

The COB Contractor performs a daily update of information on other coverage to MBD. Plans must establish connectivity with our systems, which, among other things, allows Part D plans to have direct access to other payer status information as often as their business requirements indicate. Every Federal business day, the COB Contractor pushes out updated information to MBD and then CMS sends the COB file to the Part D plans. For more information on receiving COB files, see the Plan Communications User's Guide (PCUG) available on the website at: http://www.cms.hhs.gov/MedicareMangCareSys/Downloads/PCUGv1.1%20(11.07.05).pdf. It is incumbent upon Part D plans to note any changes to other payer status included in our systems and to send that information to the COB Contractor.

Data from plans to the COB system

There is an electronic interface between Part D plans and the COB Contractor known as the Electronic Correspondence Referral System (ECRS). ECRS allows Part D plans to submit post-enrollment transactions that change or add to currently known COB information. Part D plans may send ECRS transactions in any of three possible ways: 1) by using Network Data Mover (NDM) (a secure file transfer process) to connect to the ECRS Online Application; 2) by using NDM to send an ECRS flat file; or 3) by using a current SFTP connection to send an ECRS flat file.Part D plans are updated on the status of these transactions as they move through the COB systems and informed on the determination made

by the COB Contractor on the transactions via a COB data report/file. Further information on ECRS is contained in the ECRS User Guide available on the website at http://www.cms.hhs.gov/manuals/downloads/msp105c05_att1.pdf.

The data provided by the COB Contractor on supplemental payers and order of payment is generally the best available information for Part D plans and pharmacies to act upon. However, it is important to note that Part D plans must coordinate benefits with all other payers providing coverage for covered Part D drugs, even if the COB Contractor is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Although the COB Contractor may be unaware of them, these other payers may submit claims directly to the Part D plan or through the TrOOP Facilitation Contractor, thereby enabling benefit coordination by the Part D plan. Once a plan becomes aware of these other payers, plans must submit this information via ECRS to the COB Contractor.

Plans should utilize the electronic interface established with CMS (via the MARx system) to handle plan enrollment to transmit certain other payer data elements upon enrollment and to receive daily transmissions of validated COB information. As new information about other prescription drug coverage is discovered, plans should use ECRS to send the information to CMS. Plans should not use the enrollment update transaction to communicate this subsequent information.

Beyond the electronic data transfers requirements described above, Part D plans must establish procedures for at least weekly file processing. Plans are required to not only receive information, but also apply it to their systems.

50.4 – Processing Claims and Tracking TrOOP

Part D Plans must correctly calculate the TrOOP amount in order to properly adjudicate beneficiary claims, as well as to communicate this information to plan enrollees. In order to calculate TrOOP, Part D plans will have to determine if other entities have made payments on covered drugs, and whether such payments fall under the legal definition of incurred costs (as described in 42 CFR §423.100). CMS assists in this process by providing a TrOOP Facilitation Contractor (described in Section 30.4 of this chapter) that requires that supplemental payers utilize the HIPAA coordination of benefits transaction standard, which requires the use of the NCPDP Standard Implementation Guide to communicate other payer transactions back to the primary Part D plan for purposes of tracking TrOOP in real time. Part D plans are required to process claims and track TrOOP in real time including providing known supplemental payer information to the pharmacy and by `accepting and processing N1 transactions. CMS expects Part D plans to establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicative claim reimbursements

When secondary payer information is not captured upfront in CMS systems, however, Part D plans are required to retroactively adjust claims and TrOOP balances using whatever

methodology the plan determines to be most appropriate. CMS also establishes an order of payment (see section 30.3) to the validated payer-identifying data that is transmitted to both the TrOOP Facilitator and the Part D plans from MARx via the COB file. This order of payment assists plans in processing claims when there are multiple other payers on a beneficiary's record. This is important, particularly for payers – such as SPAPs – considered payers of last resort. Because Part D plans are ultimately responsible for accurately tracking TrOOP, they are required to retroactively adjust claims and TrOOP balances when errors are made in terms of order of payment. (See section 50.15 of this chapter for further detail on reconciling payments.)

Part D plans must make timely retroactive adjustments of claims and TrOOP balances. CMS reserves the right to establish required timeframes for these adjustments based on acquired experience.
While this document is not meant to capture the TrOOP facilitation process in exhaustive detail, other sources are available in:

- Appendix A of this chapter which contains more information, in flow chart format, about what the TrOOP facilitation process entails.
- The TrOOP Faciliation Contractor website at http://www.ndchealth.com/products_services/medicarePartD_introduction.htm.
- The NCPDP Implementation Guide which is the official vehicle for establishing electronic processing rules.
- The Prescription Drug Event (PDE) Data Guidance on the website at http://www.cms.hhs.gov/DrugCoverageClaimsData/Downloads/PDEGuidance.pdf which explains TrOOP and PDE data reporting.
- Chapter 5 of this manual which will address benefits, beneficiary protections and benefit design and will contain information on incurred costs counting toward TrOOP.

50.4.1 –Receiving an N1, Without Supplemental Payer on File

Part D Plans should accept N1 transactions even in those instances where they have no supplemental payer information on file to identify the payer. CMS encourages plans to then follow up by contacting the beneficiary (which may be accomplished in conjunction with the annual COB survey of plan enrollees if that survey will be conducted within the next 2 months) to identify the supplemental payer. Once the plan receives this information, it should be transmitted to the COB Contractor for verification of the secondary coverage.

We note that in the event that a Part D plan is a secondary payer in accordance with the application of Medicare Secondary Payer (MSP) rules, the Part D plan is required to process claims in real time to support the TrOOP facilitation process.

Explanations of benefits (EOBs) provide enrollees with their year-to-date TrOOP balances and gross covered drug costs and information on the enrollees' position in the Part D benefit. To ensure enrollees are appropriately informed, CMS requires that plans develop EOBs that provide information in a form understandable to all enrollees. EOB formats are included in the Medicare marketing guidelines available on the website at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf.

50.4.2 – Beneficiary Cash Purchases

Although we expect it to happen rarely, an individual may be able to obtain a lower price at a network pharmacy than that which his or her plan charges (the plan's negotiated price) in any applicable coverage gap or deductible. This may be possible if the pharmacy is offering a "special" price or other discount for all customers, or if the beneficiary is using a discount card, and the beneficiary is in any applicable coverage gap or deductible phase of his or her Part D benefit and is able to receive a better cash price for a covered Part D drug at a network pharmacy than the plan offers via its negotiated price. In this situation, he or she may purchase that covered Part D drug without using his or her Part D benefit or a supplemental card. The enrollee's purchase price for the discounted drug will count toward total drug spend under his or her Part D benefit and TrOOP balance provided the Part D plan finds out about it.

The enrollee must take responsibility for submitting the appropriate documentation to his or her plan in order to have the amount count toward his or her total drug spend and TrOOP balances.[1] Plans must accommodate the receipt of such information directly from enrollees and adjust total drug spend and TrOOP balances accordingly consistent with their established processes and clear instructions for enrollee paper claim submissions. These processes and instructions should be designed to distinguish between claims submitted for: (1) out-of-network coverage; (2) adjustment to TrOOP balances based on wraparound payments made by supplemental payers not previously submitted to the plan; (3) documentation submitted for a purchase made via a discount card or other special cash discount rather than the Part D plan's card in any applicable deductible or coverage gap phase of the benefit; and (4) documentation submitted for a nominal copayment assessed by a PAP sponsor operating outside the Part D benefit for assistance provided with covered Part D drug costs.

We note that this lower cash purchase policy does not apply in any phase of an enrollee's Part D benefit in which he or she is liable for any less than 100 percent cost-sharing. In other words, it does not apply outside of any applicable coverage gap or deductible phase of his or her benefit. We have limited the policy's applicability in order to ensure that enrollees: (1) do not unwittingly forego plan funded coverage, which in most cases will be the lowest price available given the price concessions built into the plan's negotiated prices; (2) have the benefit of plan drug utilization review and other safety edits that can only be provided if the

[1] We note that in cases where a pharmacy offers a lower price to its customers throughout a benefit year, this would not constitute a "lower cash price" situation that is the subject of this guidance. For example, Wal-Mart recently introduced a program offering a reduced price for certain generics to its customers. The low Wal-Mart price on these specific generic drugs is considered Wal-Mart's "usual and customary" price, and is not considered a one-time "lower cash" price. Part D sponsors consider this lower amount to be "usual and customary" and will reimburse Wal-Mart on the basis of this price. To illustrate, suppose a Plan's usual negotiated price for a specific drug is $10 with a beneficiary copay of 25% for a generic drug. Suppose Wal-Mart offers the same generic drug throughout the benefit for $4. The Plan considers the $4 to take the place of the $10 negotiated price. The $4 is not considered a lower cash price, because it is not a one-time special price. The Plan will adjudicate Wal-Mart's claim for $4 and the beneficiary will pay only a $1 copay, rather than a $2.50 copay. This means that both the Plan and the beneficiary are benefiting from the Wal-Mart "usual and customary" price, and the discounted Wal-Mart price of the drug is actually offered within the Plan's Part D benefit design. Therefore, the beneficiary can access this discount at any point in the benefit year, the claim will be adjudicated through the Plan's systems, and the beneficiary will not need to send documentation to the plan to have the lower cash price count toward TrOOP.

plan adjudicates the claim; and (3) proceed through the benefit as quickly as possible in order to reach catastrophic coverage. It is unlikely that the use of discount cards or other special discounts will be a significant source of savings for most enrollees. It is possible however, depending on the cost of the drug, that if an enrollee fails to submit even one claim for a purchase made under the circumstances explained above, the enrollee will ultimately spend more than he or she would have under his or her plan's negotiated prices.

We also note that organizations or entities offering discount card or other discounted price arrangements must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty law prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

This section reflects our current beneficiary cash purchase policy, but if significant issues arise, we will revisit the policy.

50.5 – Standardized Claims Messaging

In 2007, CMS requires the rapid adoption and use of new standardized messaging procedures approved by the National Council for Prescription Drug Programs (NCPDP) in order for Part D plans to more effectively communicate with pharmacies and coordinate with other payers in real time. The adoption of new messaging will address issues that have arisen at point of sale needing clarification of certain claims adjudication responses that are specific to Part D, such as claims rejections for drugs excluded from Part D coverage and for drugs that are covered under Medicare Part B for the particular beneficiary. Further, by sending this additional information to the pharmacy, payers can expedite resolution of questions concerning how to fill the prescription and minimize staff time in answering phone calls and prior authorization processes.

Therefore, Part D Plans must promptly implement appropriate systems changes to achieve the goals of any additional new messaging approved by the industry through NCPDP to address clarifying information needed to adjudicate a Part D claim and appropriately coordinate benefits in real time. While CMS strongly encourages plan adoption and use of the standardized approach in the NCPDP guidance as issued in the 5.1 Editorial Document, until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, plans may adopt alternative approaches that achieve the goals intended in the messaging guidance.

In order to promote the use of best practices and assist beneficiaries, pharmacies and payers, CMS requires Part D plans implement an appropriate strategy that achieves the goal of the industry consensus on messaging as expeditiously as practicable after a consensus has been reached and documented by NCPDP. CMS plans to periodically review the status of plan adoption of such messaging in order to ascertain the extent that plans are following best practices in serving Medicare beneficiaries, and will issue further guidance on reporting requirements in this area at a future date.

50.5.1 – Primary Payer Use of Optional Fields to Support COB

While CMS recognizes the version C.1 (and any future version) of the NCPDP Implementation Guide as the official vehicle for establishing the special electronic processing rules to be used in coordinating benefits and generating the N1 transaction, version C.1 does not require that primary payers provide certain optional fields. The optional fields "Amount Applied to Periodic Deductible" [517-FH] and "Amount of Copay" [518-FI] in the response pricing segment of the NCPDP telecommunication standard. However, we encourage payers to use these fields to assist secondary payers in administering their benefit whenever possible. When these fields are provided by the primary payer, they can be passed from the pharmacy to the secondary payer.

50.6 – Accepting Payment of Premiums from Other Payers

As provided by the MMA, supplemental payers may wish to pay premiums on behalf of Part D enrollees instead of (or in addition to) providing wrap-around coverage. Part D plans are required to facilitate the billing and collection of such premiums. While Part D plans must accept premium payments by supplemental payers on behalf of their Part D enrollees, the details of such arrangements are strictly between Part D plans and such payers. Part D plans should ensure that in accordance with the uniform premium requirement the total premium payment for a beneficiary does not vary among plan enrollees, except in the case of employer group plans for which this requirement has been waived in part.

Under the Medicare Part D payment demonstration entitled "Medicare Demonstration to Transition Enrollment of Low Income Subsidy (LIS) Beneficiaries", CMS instituted another exception to the requirement that the total premium payment for a beneficiary not vary among plan enrollees, the de minimis premium policy. The de minimis premium policy requires Part D plans to charge full-premium subsidy eligible beneficiaries a 2007 Part D monthly beneficiary premium equal to the low-income premium subsidy amount, if the plan's beneficiary premium for basic prescription drug coverage exceeds the low-income premium subsidy amount by $2 or less. This policy only applies to LIS beneficiaries who qualify for the 100% premium subsidy. Therefore, Part D plans with premiums within the de minimis range must continue to charge their partial LIS and non-LIS beneficiaries their full beneficiary premiums.

A beneficiary must not be disenrolled from a Part D plan if it has been notified that the premiums are being paid by a SPAP or other payer and the plan has not yet coordinated receipt of the premium payments with the SPAP or other payer. In these cases, Part D plans are required to work directly with the SPAPs or the other payers to systematically coordinate and accept premium payments in accordance with the Federal regulations at 42 CFR 423.464(a)(1). That is, plans must bill the SPAP or other payers directly for the beneficiary's premium and not bill the beneficiary. Until the plan can bill the SPAP or other payers directly, plans will not be in compliance with the coordination of benefit requirements. Plans must not take any action, including sending disenrollment notices directly to the beneficiary, to disenroll the beneficiary for failure to pay premiums when the plan has failed to coordinate the collection of premiums from other payers.

Plans currently receive data from CMS in the COB file indicating which beneficiaries are covered under SPAPs. Field 111 in the Supplemental Records of the COB file (as provided

in the 2006 Medicare Advantage and Part D Enrollment and Payment Systems Changes Part IV sent to plans on September 20, 2005) indicates the type of supplemental coverage a beneficiary may have. An indicator of 'Q' identifies when a beneficiary has SPAP coverage. Plans could use this data to withhold systematic release of disenrollment notices to these beneficiaries when an SPAP is paying on behalf of the beneficiary.
In addition to accepting payment of premiums from other payers, Part D plans may wish to consider providing advance notice to such payers when an enrollee is at risk of losing coverage due to failure to pay their portion of a premium.

50.7 – Coordinating Payment of a Lump Sum for Supplemental Coverage

The MMA specifies that our COB requirements must include a method for the application by a Part D plan of specified funding amounts (a lump sum per capita method) from an SPAP for supplemental prescription drug benefits. Given that all COB requirements established with respect to SPAPs must also be applied to other entities providing prescription drug coverage, our requirements regarding the payment of a lump sum for supplemental coverage (of cost sharing) are also applicable to other payers mentioned in this guidance. Consequently, Part D plans are required to coordinate the receipt and management of lump sum arrangements with other payers. It is important to note, however, that the cost sharing funded by lump sum amounts will generally only apply toward TrOOP if made by a qualified SPAP or a charity for Part D benefits, and if made for expenditures on covered Part D drugs before a beneficiary reaches the annual out-of-pocket limit.

SPAPs (and other payers) may choose to provide their wrap-around benefits to Part D beneficiaries using four basic approaches:

1. Pay premiums for basic and/or supplemental benefits offered by Part D plans.
2. Wrap-around benefits at the point-of-sale: Pharmacy files a secondary claim to the SPAP (or its processor) for payment.
3. Contract with Part D plans on a risk or non-risk-based lump sum per capita method, i.e., solicit lump sum per capita bids from Part D plans in exchange for the provision of wrap-around benefits.
4. Provide some combination of these approaches.

CMS is establishing standards for option 3 in order to provide clear guidance on the approaches that will be deemed to be non-discriminatory among Part D plans in accordance with §1860D-23(b)(2) of the Social Security Act. These include a risk-based and a non-risk-based approach.

50.7.1 – The Risk-Based Combined Uniform Benefit/Lump Sum Contribution Approach

We believe this market-based approach is equitable to both the SPAP and the Part D plan since it establishes a benchmark payment amount derived from the submission of competitive Part D plan quotes, and balances the interests of both parties. This approach does not involve CMS in the bidding process. The following steps outline the approach SPAPs may adopt when paying lump sum per capita payments to Part D plans for wrap-around benefits in order

to be deemed non-discriminatory with respect to providing such benefits without regard to the Part D plan in which the SPAP beneficiary enrolls. Please note that this approach does not address or substitute for non-discriminatory standards with respect to education and enrollment of beneficiaries by any SPAP, or co-branding with Part D plans.

1. States that wish to adopt a lump sum per capita approach would define a uniform "benefit package" that would be available to eligible beneficiaries who enroll in Part D basic (not enhanced alternative) prescription drug coverage plans. (These wrap-around benefit packages would be subsidized by the State and would reduce cost-sharing from that included in the basic benefit to a uniform cost-sharing level. No changes would be made in plan formularies, plan pharmacy networks, or other coverage rules.) The State would be free to include risk-sharing arrangements in their defined benefit solicitation as long as identical arrangements were included in every plan contract, and as long as such arrangements would be fully reconciled prior to CMS allowable cost reconciliations with Part D plans.

2. All Part D plans in the region would be invited by the State to submit a quote (note – the quote is for the increment above basic benefits) for providing the uniform wrap-around benefit for a full-risk, lump sum per capita amount. States must use normal channels for publishing procurement notices to publicize these requests for proposals.
3. Part D plans that did not want to participate in this market would not be required to submit quotes, and States would not be obligated to provide wrap-around benefits to any beneficiaries choosing to enroll in such plans, or to promote such plans. (This does not preclude a State from providing wrap-around coverage on behalf of SPAP beneficiaries choosing to enroll in such plans, if it so chooses. In fact, if the SPAP also elects to pay the premium for all basic benefits, this approach does not permit the SPAP to exclude payment of premium for any Part D plans that do not participate in the lump sum approach.) CMS recognizes that there will be some Part D plans that will not be interested in the individual market (and will, in fact, not be available to individuals) and will not want to be required to submit their quotes to the SPAPs. Likewise, some Part D plans may not want to assume the additional (unsubsidized) risk of the lump sum per capita approach, and would not be required to enter into the bidding process.

4. Based upon the per capita quotes submitted by the plans, each State would determine what it would pay using one of the two following approaches. We believe that both approaches encourage plan participation in the lump sum approach while balancing the interests of both parties.

   A. States pay the actual quote proposed by each Part D plan**.** Under this approach, all Part D plans that wanted to participate in the lump sum per capita approach would submit their quotes. States would pay amounts based upon each Part D plan's quote, and the plans would accept full risk for the supplemental costs of the SPAP beneficiaries as specified in the defined benefit. This approach is equitable for the SPAP since it provides the option to choose this approach over the 75th percentile approach if the results of paying each plan's quote would result in lower costs to the State. It is equitable to Part D plans because SPAPs would be required to accept all quotes and no willing plan may be excluded. CMS plays no role in this process other than standard setting, and the terms of the bidding and contracting process are defined in the State's RFP and contract. **OR**

B. States pay each Part D plan an amount equal to the 75th percentile quote. This approach requires the State to pay a uniform amount to all plans based upon the Part D plan quote amount submitted at the 75th percentile. Paying all Part D plans the same amount is necessary under this approach in order to provide protection against excessively low bids, given the competitive downward pressure on bids and the lack of risk sharing. It also gives the State the opportunity to cap its payments. Those plans with quotes above the 75th percentile would need to collect the difference between the plan bid and the State's uniform contribution amount from the beneficiary in the form of an additional premium. This approach is equitable to both the SPAP and the Part D plan since it establishes a payment amount derived from the submission of competitive Part D plan quotes, protects Part D plans from excessively low bids and States from excessively high ones, and excludes no willing plans. Again, CMS plays no role in this process other than to set the non-discriminatory rules and threshold, and the terms of the bidding and contracting process are defined in the State's RFP and contract.

We note that any additional premium collected from the beneficiary attributable to the difference between the plan quote and the State's uniform contribution amount would not be a Part D premium. Therefore, it would not be consolidated with the Part D premium for purposes of withholding by SSA or plan payment determination. Any such premium must be collected directly from the beneficiary by the plan.

As part of the State's RFP and contract, any Part D plan that submits a quote would be required to accept the lump sum per capita payments made by the State under its chosen approach. Part D plans with lump sum quotes at or below the State's uniform contribution limit would have to accept the uniform contribution limit as payment in full for the provision of SPAP wrap-around benefits. (Note that some plans may be paid more than their quotes under this approach.) Under the 75th percentile option, Part D plans with quotes higher than the uniform contribution limit would have to accept the uniform payment from the State and charge the balance of the quote to the beneficiary in the form of an additional premium. Part D plans with quotes higher than the uniform contribution limit would not have the option to accept the uniform contribution and waive the additional beneficiary premium.

A Part D plan with a quote above the uniform contribution limit would be allowed to withdraw its quote if it did not wish to participate with an additional enrollee premium. However, in turn, the SPAPs would not be obliged to promote or provide wrap-around benefits to beneficiaries that join these withdrawing plans. We note that if the SPAP also elects to pay the premium for all basic benefits, this approach does not permit the SPAP to exclude payment of premium for any Part D plans that do not participate in the lump sum approach. To do otherwise would be violating the non discrimination requirements that an SPAP must provide assistance to individuals in ALL part D plans without regard to the plan in which the individual is enrolled.

5. In return, the State would have to ensure that its beneficiaries received *equal access* to enrollment in and comparable information on all the Part D plans participating in the chosen approach, without any steering to individual plans. In addition, even if a plan is not accepting lump sum payments, the State should still explain that beneficiaries can still enroll in that plan, but they will get only basic coverage – without the SPAP additional

defined benefit – if they do so. If the State has also elected to pay the premium for all Part D basic benefits, this approach does not permit the SPAP to exclude payment of premium for any Part D plans that do not participate in the lump sum approach.

Note that this guidance is not intended to address all requirements on SPAPs with respect to non-discriminatory beneficiary education, enrollment and co-branding activities. Other guidance exists on our website; for example, guidance on co-branding with SPAPs is included in the Medicare marketing guidelines available on the website at: http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/FinalMarketingGuidelines.pdf.

We recognize that under option A there is a strong financial incentive for SPAPs to steer to plans with the lowest quotes in violation of our guidance. Therefore, we forewarn States that CMS will be evaluating enrollment patterns among Part D plans. If we determine that the distribution of SPAP beneficiaries in participating Part D plans differs substantively and without good cause from the distribution of similar non-SPAP Medicare beneficiaries enrolled in those plans, CMS may conclude that the State has steered their SPAP beneficiaries towards particular plans. In this case, CMS may no longer count that State's SPAP payments towards the beneficiary's TrOOP threshold.

6. States would be required to report the results of the bidding process to CMS for oversight purposes.

7. Part D plans participating in the lump sum approach would be required to provide clear and prominently displayed information, which may include co-branding on the plan's ID card, identifying the SPAP as a co-provider of benefits under the combined approach. (This requirement is limited to coordination of benefits with SPAPs, and need not be extended to other payers unless desired by the Part D plan.)

8. Part D plans would be required to provide claims data on the State's enrollees to the SPAPs periodically in order for the State to understand the utilization underlying its costs.

We believe that this approach allows for a simplified method for SPAPs to provide supplemental (cost sharing) benefits to their beneficiaries, as well as the following additional benefits:

- Provides a seamless process from the point-of-view of beneficiaries and pharmacies
- Does not require the pharmacist to route a secondary claim.
- Eliminates the need for multiple wrap-around methods on the part of the State
- Relieves SPAPs of obligation to provide wrap-around benefits for plans that do not accept the lump sum payment
- Establishes a fair and equitable lump sum amount based on competitive market forces
- Makes additional risk bearing optional for Part D plans
- Although not required for other payers, this approach could work just as well for other payers, if desired.

50.7.2 – The Non-Risk-Based Lump Sum Payment with Claims Reconciliation Approach

States that wish to fully subsidize a fixed portion of beneficiary cost sharing through their SPAPs may do so as long as an equal subsidy amount is offered to each beneficiary in each Part D plan. (This uniform payment requirement would not preclude reimbursement of subsidy amounts in the event a given beneficiary did not incur the entire amount of cost sharing.) These subsidy amounts would need to be applicable to any enrollee cost sharing and not be tied to any particular benefit design, such as the deductible or coverage gap, so that they would be applicable to every Part D plan basic benefit design. Part D plans would enter into arrangements to receive such subsidies and to apply the subsidy amounts to first dollar coverage of cost sharing for each applicable beneficiary. Part D plans would be required to provide claims data on the State's enrollees to the SPAPs in order for the State to understand the utilization underlying its costs, and for reconciliation of paid to incurred amounts.

The regulation at 42 CFR 423.464(a) requires that Part D plans must coordinate with SPAPs and other entities providing other prescription drug coverage. This includes if the SPAP or other payer is adopting a lump sum per capita approach when supplementing Part D benefits in accordance with section 42 CFR 423.464(a)(2). Therefore, CMS requires all Part D plans to have the capacity to participate in non-risk based arrangements, if offered by the State, SPAPs or other payers so that their beneficiaries can receive coordinated, wrap-around coverage at the point-of-sale. If a plan is out of compliance with this regulatory requirement, CMS will not disqualify a state program from its qualified SPAP status. CMS will not view SPAPs as discriminating, in violation of section 1860D-23(b)(2) of the Act, due to a Part D plan's failure to adhere to this COB requirement.

50.8 – Claims Reconciliation Reports

Except for the non-risk-based lump sum with reconciliation approach described in section 50.7.2, above, we do not believe there is any need for claims reconciliation reports. In general, States (and other payers) will either receive secondary claims through their own processors, or they will coordinate using approaches that do not require claim reconciliations.

50.9 – Transferring TrOOP Balance When a Beneficiary Changes Part D Plans

Part D rules require plans to track the beneficiary's TrOOP and correctly apply these costs to the TrOOP limit in order to provide the catastrophic level of coverage at the appropriate time. The TrOOP threshold is calculated on an annual basis and must be transferred between Part D plans if a beneficiary disenrolls and re-enrolls at any time before the end of a coverage year. Plan collection, and transfer if appropriate, of the TrOOP and gross covered drug spending balances are essential for plans to correctly manage the Part D benefit.

In 2006, the TrOOP balance transfer or explanation of benefits (EOB) transfer process was first implemented to facilitate the required coordination of benefits between plans, and the plan-to-plan transfer of TrOOP and total drug spend balances for beneficiaries affected by the

Enrollment Reconciliation process. CMS continues to require its use to transfer TrOOP-related data whenever beneficiaries transfer from one plan to another during the coverage year. This will remain a requirement until an automated process is implemented to replace it.

As a required first step in the process, Part D plans are requested to populate the "EOB Transfer Contact" field in the Health Plan Management System (HPMS). To enter this information, plans need to follow this navigation path: HPMS Homepage > Contract Management > Contract Management > Select Contract Number > Contact Data > EOB Transfer Contact. CMS maintains a periodically updated posting of these contacts that is available in the downloads section at http://www.cms.hhs.gov/PrescriptionDrugCovContra/.

When a plan receives a disenrollment transaction with a transaction reply code of [014] or [015] indicating that a member has disenrolled, the disenrolling plan must create a special transfer EOB. This EOB must be created regardless of whether or not the disenrolled beneficiary had claims activity. The transfer EOB must contain information concerning the beneficiary's TrOOP balance and gross covered drug costs and must be sent to the new plan of record. The Source File ID field on the Transaction Reply Report (TRR) identifies the contract number of the plan of record that will receive the EOB which can be used to locate the contact information posted as described above. The Transfer EOB must be sent to the new plan of record within seven days of the date of the disenrollment TRR.

Because these data are essential to the accurate positioning of the beneficiary in the benefit by the new plan of record, should the TrOOP balance or gross covered drug costs change after an EOB has been sent, the disenrolling plan must send both the beneficiary and the new plan of record an updated EOB reflecting the new total TrOOP and gross covered drug spend balances. Any updated EOBs must be included in the set of EOBs sent by the 15th of the month following the change.

If the total number of beneficiary records to be transmitted to any one plan of record is less than 100, this information may be in the form of a paper copy EOB. Note that only the two relevant fields need be filled in, and there is no need to send a complete EOB that includes proprietary pricing detail. If 100 or more records must be transmitted to a new plan of record, the disenrolling plan must create an Excel file in the format shown below.

Transfer EOB Format

A	B	C	D	E
HICN	Transfer Out Plan Contract Number	Effective Date	TrOOP Balance	Gross Covered Drug Costs

The effective date to be entered in Column C is the date through which the Column D and E balances were calculated.

50.9.1 –Transfer EOBs Transmission

Paper copy EOBs may be faxed to the EOB Transfer Contact specified in HPMS for the plan of record or shipped through a common carrier to the Contact either as paper copy EOBs or scanned copies on a CD-ROM. Excel files must be shipped on a CD-ROM through a common carrier. A cover sheet should accompany the EOB Transfer data and include a contact should the receiving plan have questions or require followup.

When creating Transfer EOBs for fax transmission, plans should use a font that is large enough for the EOB data to be legible even after multiple faxes.

50.9.2 – Exceptions Process

In the process of EOB transfer, should a plan receive EOB information for a beneficiary who is not in their plan, contact should be made with the EOB Transfer Contact at the plan that sent the EOB information to resolve the problem. The plan sending the EOB is responsible for promptly querying CMS systems or contacting CMS to identify the plan of record and for reissuing the transfer EOB data.

In 2007, CMS will be exploring a process to automate the transfer of a Part D beneficiary's true-out-of-pocket (TrOOP) and gross covered drug spending balances between plans that a beneficary is enrolled in during the coverage year. Part D rules require plans to track the beneficiary's true-out-of-pocket (TrOOP) and correctly apply these costs to the TrOOP limit in order to provide the catastrophic level of coverage at the appropriate time. Because the TrOOP threshold is calculated on a annual basis, it must be transferred between Part D plans if a beneficiary disenrolls and re-enrolls at any time before the end of a coverage year. Plan collection, and transfer if appropriate, of the TrOOP and gross covered drug spending balances are essential for plans to correctly mange the Part D benefit.

In designing an automated process, CMS is exploring various options, ranging from plans transmitting the beneficiary's total TrOOP and gross covered drug costs only upon a beneficiary mid-year disenrollment to plans routinely (e.g., monthly) reporting these totals for all beneficiaries when explanation of benefits (EOB) reports are created.

50.10 – Special Transition Period for Retroactive Enrollment Situations

For 2007, CMS is implementing a special transition period with important COB implications that requires Part D plans provide limited reimbursement for covered Part D drugs for a time immediately preceding the minimum 30- or 90-day transition period. This requirement applies to those situations involving claims incurred by, or on behalf of, a beneficiary who has subsequently been retroactively enrolled in a Part D plan by CMS. These situations almost exclusively involve beneficiaries who are full-benefit dual eligibles. The special transition period will be available to all beneficiaries.

Although CMS is working with the States to identify as many individuals as possible in advance of the date they will become dually eligible in order to minimize issues involving retroactivity, there will be some situations we will not be able to identify in advance. Because eligibility for Medicaid may be retroactive for up to three months prior to the month in which the Medicaid application was filed and Medicaid applications frequently require significant time for the State to process, periods of retroactivity will continue to be several months in duration. We expect that this problem will usually be mitigated by the fact that, as a Medicare beneficiary, the individual will have had an opportunity to enroll in a Part D plan and apply for the low-income subsidy. For those who do enroll in a Part D plan, and then are retroactively eligible for Medicaid, the effective date of their Part D plan enrollment is the later of the first of the month the beneficiary is dually eligible, or January 2006.

For 2006, with respect to claims incurred during a period covered under actual Part D enrollment, Part D plans were responsible for paying or reimbursing the costs of a beneficiary's Part D covered drugs to the extent that the plan would have paid as a primary payer. If the beneficiary's existing drug regimen required prior authorization or included non-formulary drugs and the retroactive period preceded the plan's transition period, this may have resulted in gaps in coverage. Coverage gaps may also have resulted from out-of-network pharmacy status or pricing in excess of the plan's negotiated rates that have been paid by the beneficiary or another payer on the beneficiary's behalf.

In 2007, we are requiring plans to provide a special transition period to accommodate claims incurred during a no greater than seven-month retroactive eligibility. The special transition period will be available to all beneficiaries. During this special transition period, normal transition rules will apply, but plans will be responsible for the allowable charges paid by other third party payers for all Part D drugs, including non-formulary drugs provided outside the transition period and formulary drugs with prior authorization requirements. The beneficiary, or CMS in the case of low-income subsidy individuals, will be responsible for any out-of-network or pricing differentials. Plans need to accommodate and facilitate requests for reimbursement of claims incurred during these periods. CMS prefers that plans, to the extent they are able, do this electronically rather than by processing paper claims.

50.11 – Sharing Formulary Information with Other Payers

Although Part D plans may share detailed information about their formularies (in electronic format) with other payers upon request, there is no specific requirement that they do so. CMS has made the Medicare Prescription Drug plan information available for purchase in Public Use Files (PUFs). These files contain all of the plan and formulary data for all of the plans with the exception of the pricing data which is considered proprietary. This is the only data set that is publicly available. Further information is available at http://new.cms.hhs.gov/NonIdentifiableDataFiles/09_PrescriptionDrugPlanFormularyandPharmacyNetworkFiles.asp.

In addition, as required by 42 CFR 423.120(b)(5)(i), plans will be required to inform other payers of formulary changes (whether formulary deletions or changes in the tiering status of a drug) at least 60 days in advance of such a change. This may be accomplished by means of posting this information on Part D plan websites.

50.12 – Sharing Claims Data

We do not have the authority to require data exchanges between Part D plans and the States except as required for COB purposes. While the MMA requires Part D plans to allow SPAPs and other entities providing prescription drug coverage to "coordinate" with them, this language does not support requiring coordination of anything but payment. However, we strongly encourage Part D plans to independently share historical and ongoing data on these shared enrollees with other payers – particularly with States – provided such disclosure is consistent with the requirements of the Health Insurance Portability and Accountability Act of l996 (HIPAA) Privacy Rule. We encourage Part D plans to discuss reciprocal arrangements with State Medicaid Plans under which Part D plans would provide Part D drug claims data in exchange for both historical prescription drug claims data and ongoing medical claims (particularly diagnoses) on the dual eligible population to assist with medication therapy management and other quality assurance programs. We also encourage plans to provide for this reciprocal data exchange without the charging of user fees.

Part D plans and States may negotiate the details regarding the development of a Standard File Format for Patient Drug History and Standard Data Sharing Agreement. NCPDP, which is the national standards organization for pharmacy claims, has adopted the "Post Adjudication Standard". Section 10 of the "Post Adjudication Standard Implementation Guide, Version 1.0" contains the "Post Adjudication Utilization Record" which is the recommended standard record States and Medicare Part D Plans could use to exchange drug history information. In order to access the NCPDP documentation and use the Post Adjudication Utilization Record, the States and/or their contractors must be members of NCPDP.

If the States and Medicare Part D Plans agree to exchange enrollees' drug history information, states and plans are new business associates. It is therefore necessary that the exchange of data complies with the requirements of HIPAA. To accomplish this, a Patient Drug History Data Sharing Agreement signed by the Medicare Part D plan and the State must be in place prior to executing file transfers between these entities.

We believe States have the authority under 42 USC §1396a(a)(25) to request information to coordinate benefits States may have paid under the State Medicaid program. CMS will be issuing guidance to States regarding the implementation of these statutory requirements. We encourage Part D plans to review 42 USC §1396a(a)(25) as well as the related CMS guidance.

50.13 – Applying Medicare Secondary Payer (MSP) Requirements

The MMA extended MSP laws applicable to MA organizations to Part D sponsors. Accordingly, Part D sponsors will have the same responsibilities under MSP laws as do MA plans, including collection of mistaken primary payment from insurers, group health plans,

employer sponsors, enrollees, and other entities; and the interaction of MSP rules with State laws. Part D plans must properly apply MSP laws and regulations to their payments (e.g., working aged, workers' compensation (WC)). This section provides clarification regarding a limited number of MSP situations; however, Part D plans are required to apply all MSP laws whether or not they are specifically mentioned here.

50.13.1 – Workers' Compensation

Payment under Medicare may not be made for any item or service when payment has been made, or can reasonably be expected to be made, for such item or service under a WC law or plan of the United States or any state. CMS recognizes that diagnostic information is not collected at the point of sale, however, we expect Part D plans to make good faith efforts to identify claims associated with WC.

It is, therefore, imperative that Medicare's interests be protected when parties enter into workers' compensation (WC) settlements. One method of protecting Medicare's interest in a WC situation is a Workers' Compensation Medicare Set-aside Arrangement (WCMSA), which allocates a portion of the WC settlement for future medical and future prescription drug expenses. "Future medicals and future prescription drugs" are those services and items provided after the final WC settlement. CMS reviews WCMSA proposals for Medicare beneficiaries with WC settlements greater than $25,000 and also for individuals who are within 30 months of Medicare entitlement and possess a WC settlement greater than $250,000. For additional information with regard to CMS' WCMSA policy and procedures, please visit http://www.cms.hhs.gov/WorkersCompAgencyServices.

WCMSA funds are administered by the claimant or a professional administrator employed by the workers' compensation employer, carrier or the claimant. CMS keeps a record of the WCMSA amount determined by CMS to be adequate to protect Medicare's interests with regard to the claimant's future medical treatment and/or prescription drug expenses. The claimant/professional administrator is responsible for submitting an annual attestation form or professional accounting to the Medicare contractor. This document attests that the claimant has appropriately expended the WCMSA funds for that year.

In order to assist the Part D plans in making proper payments with regard to WCMSAs, CMS will provide the Part D plans with the WCMSA amount. The WCMSA amount is the combined amount for future medical and future prescription drug costs related to the WC injury. Exhaustion of the combined WCMSA amount includes both services (i.e., future prescription drug treatment and future medicals). For example, if the total WCMSA amount provided to the Part D plans is $10,000, this amount can include $7,000 for future prescription drug treatment and $3,000 for future medical expenses. However, it is important that the Part D plans understand that even though the total WCMSA amount is $10,000, the final actual expenditures could be $6,000 for future prescription drug treatment and $4,000 for the future medical expenses, which will still appropriately exhaust the WCMSA.

When the funds in a WCMSA are exhausted, the Part D plans must notify CMS so that the MSP occurrence may be terminated. This is currently accomplished by reporting the exhaustion of the WCMSA to the COB Contractor.

50.13.2 – Flexible Savings Accounts (FSAs), Health Savings Accounts (HSAs), Archer Medicre Savings Accounts (MSAs), and Health Reimbursement Accounts (HRAs)

Part D plans should not require beneficiaries to use the funds in their FSAs, HSAs, or MSAs before making payments when the group health plans attached to such accounts are primary under the MSP laws. However, under the MSP group health plan laws (e.g., when a beneficiary with current employment status has an HRA through his employer), plans should make secondary payments after HRA funds are used.

When a beneficiary is non-working, an HRA is secondary to Medicare, but drug costs paid or reimbursed from the HRA are not TrOOP-eligible.

50.14 – Executing Business Associate Agreement with TrOOP Contractor

Consistent with the HIPAA Privacy Rule (45 CFR Parts 160 and 164), the TrOOP Facilitation Contractor will be a business associate of Part D plans for the purpose of performing TrOOP and COB functions. Accordingly, each Part D plan will be required to execute a business associate agreement with the TrOOP Facilitation Contractor covering TrOOP and COB functions. Please note, however, that pharmacy benefit manager (PBM) subcontractors to Part D plans will not be required to enter into separate business associate contracts with the TrOOP Facilitation Contractor, since data at the PBM will be protected through business associate agreements between the Part D plan and the PBM. To facilitate the execution of these agreements between the TrOOP Facilitation Contractor and the Part D plan sponsors, a standard language business associate agreement has been developed by CMS and sponsors are strongly encouraged to sign this agreement without modification.

50.15 – Payment Reconciliation

Because of program start-up issues in 2006, lags in the information available to pharmacies at the point-of-sale regarding which Part D plan to bill may have resulted in the pharmacies' having access to outdated or incomplete information. Because pharmacies generally relied in good faith on this information, in some cases the wrong payer paid for a prescription. Given the volume of drug claims that pharmacies would need to re-adjudicate as a result of incorrect Part D enrollment information available at the point-of-sale, re-adjudication would have imposed a significant administrative and financial burden on pharmacies. Therefore, payer-to-payer reconciliation procedures were developed to mitigate the administrative and financial burden involved with re-adjudication of claims.

Although this payer-to-payer process was designed initially to be a temporary measure during Part D's start-up phase, CMS is requiring that plans continue to use the special processes established in 2006. In addition, unforeseeable future events may create further need for processes to reconcile payments when a payer other than the correct Part D plan of record pays as primary for a covered Part D drug for an enrolled beneficiary. These other

reconciliation processes may be developed by CMS to accomplish payment reconciliation without involving pharmacy reversal and re-adjudication of claims or the public release of a payer's proprietary information, such as negotiated rates.

50.15.1 – Plan-to-Plan Reconciliation during Transition Periods

The opportunity for beneficiaries to change their Part D plan enrollment during the coverage year creates situations in which, due to lags associated with the enrollment process and information systems updates, the plan from which a beneficiary has transferred makes payment for covered prescription drug costs incurred after the effective date of the beneficiary's enrollment in the new plan of record. In 2006, CMS developed a plan-to-plan payment reconciliation process with plan participation. PDE guidance describing this process is available on the website at: http://www.cms.hhs.gov/DrugCoverageClaimsData/Downloads/P2PReconInstructionsPhase1.pdf. To address payment reconciliations that are required to resolve these enrollment transition issues, CMS will continue to explore the plan-to-plan reconciliation and reimbursement process in 2007. In the interim, plans will continue to use the special prescription drug event submission and reimbursement processes established in 2006. A transition period for this process of a minimum of 30 days is required

An outstanding issue that will be considered relative to this process is that, although our 2006 clarifications of the transition process specified circumstances in which claim denials or edits were allowable, the plan-to-plan reconciliation process as designed precludes plan use of these edits in the transition period. That is, the process's design reflects the consensus of plan participants to prevent disclosure of proprietary pricing information by masking the NDC coding.

50.15.2 – Other CMS-Defined Reconciliation Processes

Unforeseeable events in the future may create the need for processes that would require Part D sponsors to coordinate benefits on a timely basis with other third parties and use CMS-developed reconciliation processes, when established, in situations in which a payer other than the correct Part D plan of record pays for covered Part D drug costs as a primary payer. For example, this was the case in 2006 with respect to the State-to-Plan Reconciliation Project in which some States made drug payments for dual eligible beneficiaries and low-income subsidy entitled beneficiaries enrolled in Part D and were subsequently reimbursed by CMS through a special demonstration authority. Processes, similar to the State -to-Plan Reconciliation process employed in 2006, may need to be developed by CMS in lieu of requesting pharmacy claims reversals and re-adjudications or the public release of a payer's proprietary information (such as negotiated prices).

50.15.3 – Retrospective Resolution Directly with Other Payers

The plan-to-plan reconciliation process resolves those situations in which a Part D plan other than the plan of record paid claims for a beneficiary during the initial transition period. However, situations will continue to arise outside the plan-to-plan process in which other payers that are not Part D plans either pay, but should not have paid at all, or pay more than

they should have because they paid out of the correct payer order. In these situations, Part D plans are required to work with these providers of other prescription drug coverage to resolve these payment issues. Other payers are entitled to seek compensation from the Part D plan once the Part D enrollment is confirmed. The plan should have a process in place to handle the payment resolution and this process should not be restricted by the implementation of timely filing requirements.

Further, Part D plans must determine whether or not any amount paid by these other payers was TrOOP-eligible and must adjust, as necessary, the affected beneficiaries' TrOOP balances. For example, the Indian Health Service (IHS), Tribes and Urban pharmacies are non-TrOOP eligible payers when Federal funds are utilized.

As noted in the discussion of IHS/Tribal health coverage in appendix C, some Tribes may use exclusively non-Federal funding to pay Part D coverage on behalf of American Indian and Alaska Native (AI/AN) Medicare beneficiaries when receiving services through I/T/Us and other Part D providers. To the extent that a Tribe uses only non-Federal funding for all its medical services, payments made on behalf of AI/AN beneficiaries for Part D cost-sharing may count toward TrOOP (provided no other sources of funding otherwise render it a government-funded health program). Therefore, Part D plans must ensure that they have a process in place to distinguish among Tribes whose Part D cost-sharing payments count toward TrOOP (those that are exclusively non-Federally funded) versus those whose Part D cost-sharing payments do not count toward TROOP (those that, for example, receive any Federal or other government funding for medical services). Many Tribal payments may not be made on an on-line real-time basis and it may be difficult for plans to recognize those that are TrOOP-eligible. In light of the difficulty, plans when approached by beneficiaries, or by Tribes on their behalf, must have a process to make retroactive adjustments of TrOOP balances.

50.15.4 – Plan Re-adjudication versus Pharmacy Reprocessing

If the total payment to the pharmacy for a claim was correct, however the plan subsequently determines that an adjustment is required that does not affect the total payment, but does alter the plan-beneficiary liability split, the plan must re-adjudicate the claim within its own system without involving the pharmacy. This is most likely to occur when the plan corrects low-income beneficiary cost-sharing subsidy levels.

Part D plans are encouraged to avoid pharmacy reprocessing, but CMS recognizes that reversals may be appropriate under certain circumstances. Plan requests for pharmacy reprocessing should in general be limited to those situations where the total payment to the pharmacy changes, for example, in situations involving a pricing error. Plans are responsible for reimbursing or collecting amounts from beneficiaries that result from the reprocessing of these claims and should not transfer this responsibility to pharmacies.

50.15.5 – Claims Filing Timeframes

A number of issues associated with Part D, such as multiple payers, payer order, and retroactive eligibility, create challenges for coordinating benefits among Part D plans and other providers of prescription drug coverage. When all payer information is available at the

point-of-sale, pharmacies typically serve as the intermediary facilitating coordination between Part D plans and other payers. However, when the information necessary to identify the correct primary payer for Part D drugs provided to Medicare beneficiaries enrolled in Part D plans is lacking, pharmacies may, through no fault of their own, bill the State and other payers instead of a beneficiary's Part D plan.

CMS addressed a major portion of these situations occurring during the first quarter of 2006 through special one-time reconciliation processes. The balance of these situations, as well as those occurring subsequently, may some times require resolution through claims reversal and rebilling. In their role of facilitating coordination between Part D plans and payers, some pharmacies are agreeing to reverse incorrect claims and bill the proper Part D plan. We believe that in those circumstances in which the pharmacy is not at fault it would inappropriate for Part D plans to impose the conventional 30-90 day timely filing limits rather than a less restrictive timeframe, as this industry standard generally applies only when the pharmacy is in a position to correctly bill, but fails to do so. We also believe that this process is appropriate for use in the Point of Sale Facilitated Enrollment process when incorrect health insurance claim numbers (HICNs) were used.

To ensure effective coordination between Part D Plans and SPAPs and other entities providing prescription drug coverage, CMS required Part D Plans to implement a 180-day timely claims filing limit for claims incurred January 1 through June 30, 2006. This afforded pharmacies when not at fault for the original billing error adequate opportunity to reverse and rebill such claims. This claims filing window was necessary to accommodate the identification and resolution of coordination of benefits issues requiring claims reversal and rebilling to appropriate payers.

For 2007, in lieu of a requirement for a 180-day timeframe, CMS requires plans to establish at least a 90-day claims filing timeframe and to make appropriate allowances for COB claims on a case-by-case basis. Once the next HIPAA coordination of benefits transaction standard for retail pharmacy drug claims is effective, Part D plans could consider using certain delay reason codes in the external code list, specifically those that specify the reason for the delay in claims submission, in field number 357-NV to differentiate COB-related delays from other types of delays.

60 – Coordination of Benefit Activities of Non-Part D Payers

60.1 – Reporting the Existence of Prescription Drug Coverage Provided to Enrollees

As discussed in section 30.1 of this chapter, we expect that other payers will provide information regarding any other prescription drug coverage that their Medicare enrollees may have. As noted in section 40.1, Medicare beneficiaries are required to disclose this information to Part D plans; consequently, other payers responsible for payment or reimbursement of Part D claim cost sharing should assist their enrollees in discharging this obligation. There are certain legal requirements to inform CMS when another payer provides coverage that is primary to Medicare under the MSP laws (e.g., employers sent the Data Match questionnaire described later in this chapter, the 42 CFR 411.25 notice requirement). For this required MSP reporting, affected entities should use the MSP-specific reporting methods CMS requires (e.g., Data Match forms) or provides (e.g, VDSA in lieu of Data

Match forms). However, for seamless benefit coordination and accurate TrOOP accounting, we strongly encourage payers to report their coverage information even when it is not legally required.

To do this, CMS makes available a direct and easy data exchange process through a vendor, the COB Contractor. A data exchange with CMS allows other payers:

1. To assist beneficiaries in fulfilling their statutory obligation to disclose third party reimbursement for Part D drug costs.
2. To avoid the cost of paying as primary when the payment should be secondary to Part D.
3. As a plan of record, to be notified if a paid claim is reversed or adjusted outside an on-line adjudication process.
4. If TrOOP-eligible, to cease payments for beneficiaries receiving the full low-income subsidy who reach the catastrophic phase of the benefit, since at that point, Medicare fully subsidizes the beneficiary's incurred costs for covered Part D drugs.

The data exchange agreements require payers to periodically submit an input file containing certain enrollee populations. In return, the payer will receive a response file from the COB Contractor indicating which of its enrollees are Medicare Part D beneficiaries. For more information about the COB process offered by CMS, see: the Part D COB website currently available at http://www.cms.hhs.gov/COBGeneralInformation/.

60.2 – Obtaining and Reporting Rx Identifiers

Payers supplemental to Medicare should obtain a unique RxBIN and/or PCN combination that will identify their paid claim responses for TrOOP tracking purposes for those situations in which Part D is the primary payer. We recommend that payers obtain a RxBIN and/or PCN combination unique to each separate plan they offer in order to distinguish among all of their plans. This allows each benefit plan to fulfill its obligation as a supplemental payer if it is identified on the COB file as secondary coverage.

In order for Rx identifier information to be available at point-of-sale through the TrOOP Facilitation Contractor and Part D plans, payers must report these unique identifiers to CMS through the COB reporting process described in section 30 of this chapter. Payers primary to Medicare will continue to use their existing BIN and/or PCN.

NOTE: Not all other prescription drug coverage will have Rx identifiers. For instance, incident-driven coverage, such as Worker's Compensation, does not normally provide electronic, point-of-sale benefits and thus does not need such identifiers; also SPAPs that only offer premium assistance will not have them.

60.3 – Supplying Claims Information When a Supplemental Payment Is Made

In order for the COB and TrOOP tracking processes to function as effectively as possible, other payers should supply paid claims information to the Part D plan after making a payment that is supplemental to a Medicare payment. This will happen automatically if the other payer reports their coverage information to CMS in accordance with the processes

described in Section 60.1 of this chapter with the appropriate Rx BIN and/or PCN combination to enable the TrOOP Facilitator to identify the supplemental payer's status.

However, if the other payer is aware that the TrOOP facilitation process was not used for some reason, or if the other payer does not have electronic claims capability, the payer may alternatively submit paper claims or make arrangements to submit information in another format in order for the data to be available for TrOOP calculations by Part D plans. Further information on the batched claims process is available on the TrOOP Facilitator's website at http://medifacd.ndchealth.com/Payers/MediFacD_Payers.htm#SupFacBatch.

60.4 – Coordinating with Part D Plans for Payment of Premiums

If one of the "other payers" listed in 42 CFR 423.464 chooses to pay Part D premiums on behalf of its members who are enrolled in Part D plans, that payer should coordinate directly with the Part D plans in question. Part D plans are required to allow and facilitate premium payment coordination with other payers. If the plan fails to comply with this requirement, it cannot disenroll a beneficiary for failure to pay premiums. Further discussion on coordination of premiums is contained in section 50.6 of this chapter.

60.5 – Following Medicare Secondary Payer (MSP) Laws and Order of Payment Standards

MSP laws apply to all payers, including those providing prescription drug coverage, and all payers are legally required to make themselves aware of and follow such laws. This chapter provides clarification regarding the limited number of MSP situations described below; however, payers are required to know and apply all MSP laws whether or not they are mentioned in this chapter.

60.5.1 –IRS/SSA/CMS Data Match

IRS/SSA/CMS Data Match requirements pursuant to the Consolidated Omnibus Budget Resolution Act of 1989 (COBRA '89) apply to prescription drug coverage. Employers required to complete Data Match forms must include prescription drug information – including their ordinary RxBINs, PCNs, RxGRPs, and RxIDs – on their Data Match forms. Data Match requirements may be fulfilled by obtaining a VDSA, (see section 30.1 of this document for a brief description), and providing coverage information through that process. Note that for Data Match and other MSP purposes, payers primary to Medicare do not need to report the unique RxBIN and PCN combination they acquired for TrOOP purposes because MSP claims do not go through the TrOOP facilitation process. (However, beneficiary cost sharing on Part D plan claim payments as a secondary payer will count toward TrOOP.)

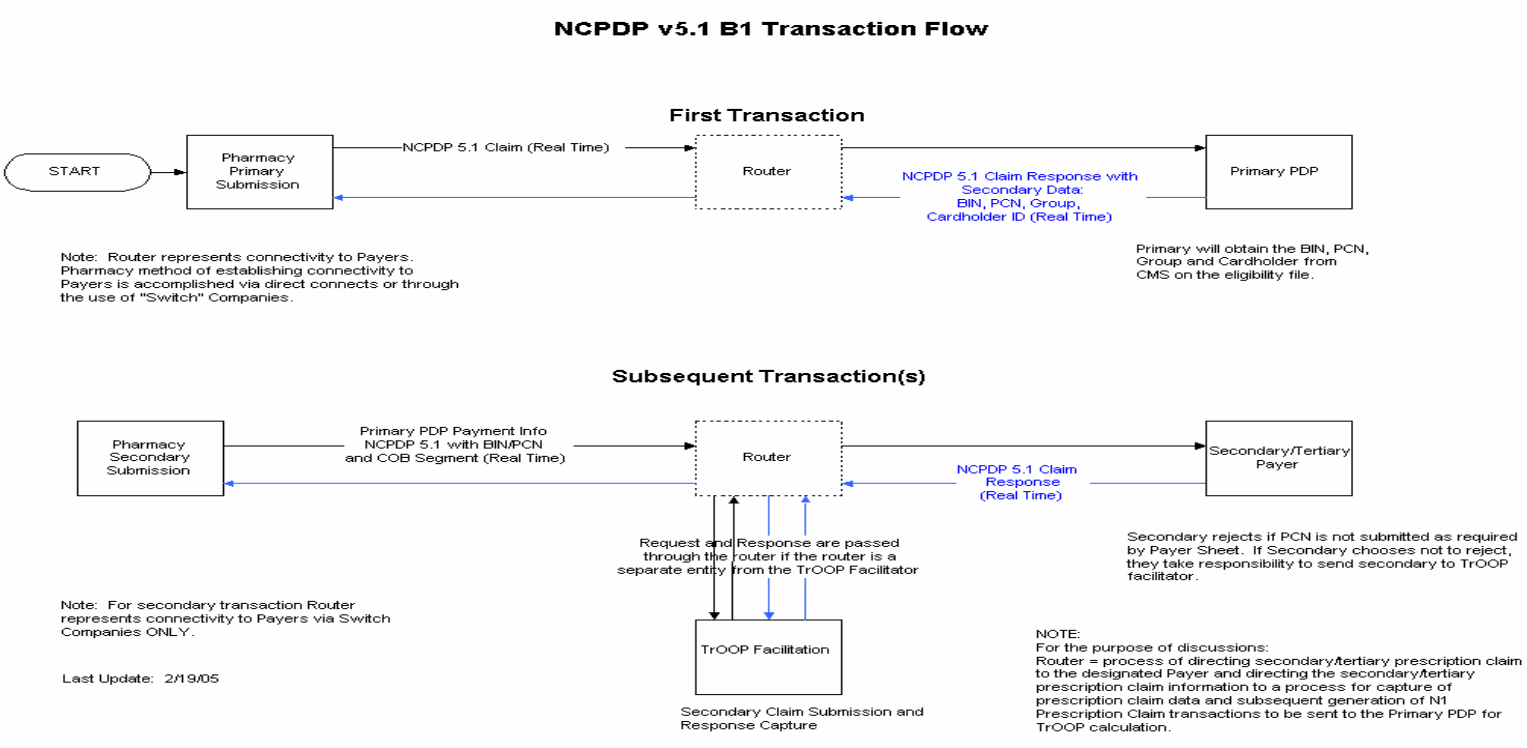
60.5.2 –FSAs, HSAs, MSAs, and HRAs

Payers that are required to report group health plan coverage to CMS under the MSP laws do not have to report the FSAs, HSAs, or MSAs that may be attached to such coverage. However, HRAs are group health plans, and payers should report HRAs to CMS in the same

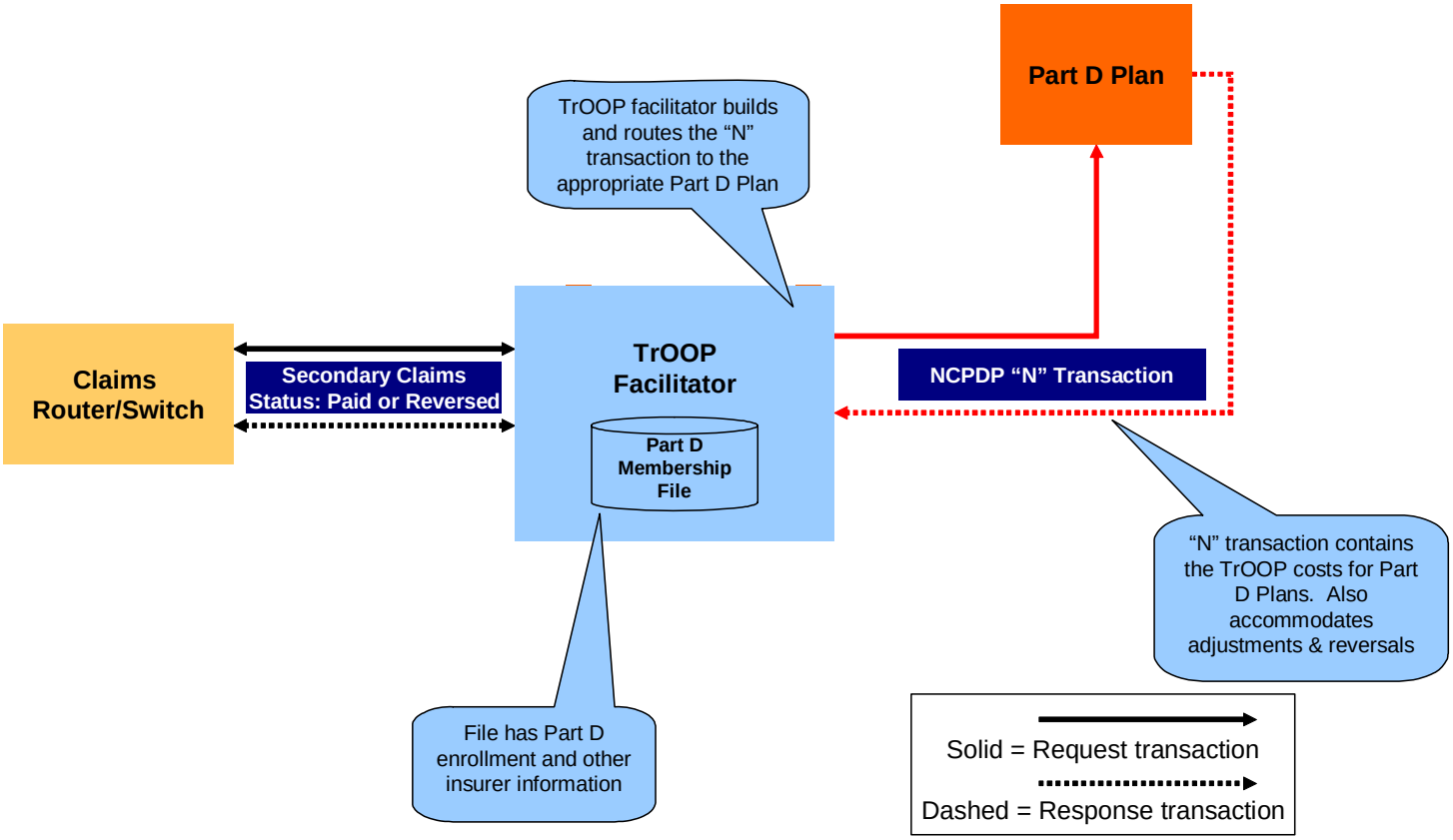
manner as group health plan information is reported. Note that all of these accounts must be structured to comply with Federal laws, including laws that may restrict their use by Medicare beneficiaries.

Appendix A – TrOOP Facilitation Process

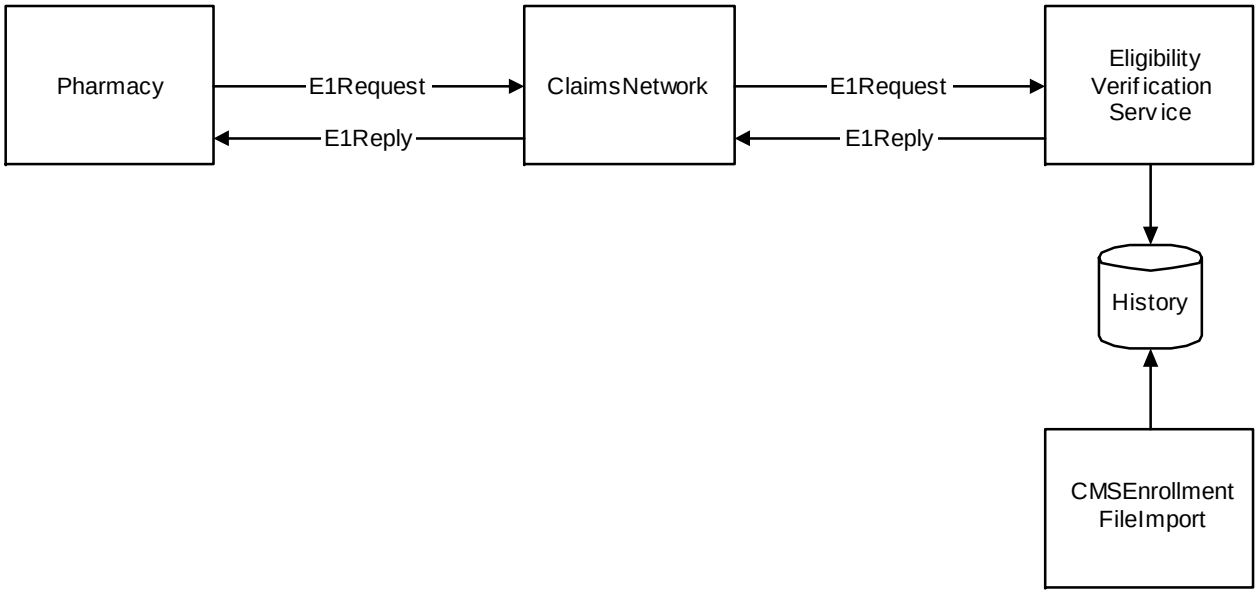
Appendix A: TrOOP Facilitation Process



TrOOP Facilitation



Eligibility Transaction



Appendix B – COB Survey

MEDICARE QUESTIONNAIRE FOR BENEFICIARIES WITH PRESCRIPTION DRUG COVERAGE

NAME | DATE OF BIRTH | MEDICARE NUMBER

SECTION A - INFORMATION ABOUT YOU

1) Are **YOU** currently employed? **YES** ☐ **NO** ☐ (If **NO**, go to **SECTION B**)

2) Do **YOU** have any group health plan coverage through your current employer?
YES ☐ **NO** ☐ (If **NO,** go to **SECTION B**)

3) How many employees, including yourself, work for your employer?
Don't know ☐ **1-19** ☐ **20-99** ☐ **100 or more** ☐

Please provide information about the employer and the employer group health plan in the spaces below:

EMPLOYER NAME

ADDRESS

ADDRESS

CITY STATE ZIP

NAME OF GROUP HEALTH PLAN

ADDRESS

ADDRESS

CITY STATE ZIP

GROUP IDENTIFICATION NUMBER

DATE INSURANCE COVERAGE BEGAN (M M – D D – Y Y Y Y) POLICY NUMBER

4) Does your employer group health plan cover prescription drugs? **YES** ☐ **NO** ☐ (If **NO**, go to **SECTION B**)
Please use your insurance card to provide the following information if available:

Rx GROUP Rx PCN

MEMBER ID Rx BIN

SECTION B - INFORMATION ABOUT YOUR HUSBAND/WIFE/FAMILY MEMBER

1) Is your family member currently employed? **YES** ☐ **NO** ☐ **N/A** ☐ (If **NO** or **N/A**, go to **SECTION C**)

Husband/Wife/Family Member's Name

First Husband/Wife/Family Member's Social Security Number

Last

2) Does your husband/wife/family member have group health insurance coverage through their employer?
YES ☐ **NO** ☐ (If **NO**, **STOP**, go to **SECTION C**)

3) How many employees including your family member, work for the employer from whom they have health insurance?
Don't know ☐ **1-19** ☐ **20-99** ☐ **100 or more** ☐ (if **less than 20**, **STOP**, go to **SECTION C**)

(TURN PAGE OVER)

SECTION B - INFORMATION ABOUT YOUR HUSBAND/WIFE/FAMILY MEMBER, CONTINUED

4) Does your husband/wife/family member's employer group health plan cover prescription drugs?

YES ☐ **NO** ☐ (If **NO**, go to **SECTION C**)

Please use your husband/wife/family member's insurance card to provide the following information if available:

Rx GROUP

Rx PCN

MEMBER ID

Rx BIN

Please provide information about the employer and the employer group health plan in the spaces below:

EMPLOYER NAME

ADDRESS

ADDRESS

CITY STATE ZIP

NAME OF GROUP HEALTH PLAN

ADDRESS

ADDRESS

CITY STATE ZIP

GROUP IDENTIFICATION NUMBER

DATE INSURANCE COVERAGE BEGAN (M M – D D – Y Y Y Y)

POLICY NUMBER

SECTION C - INFORMATION ABOUT YOUR SUPPLEMENTAL COVERAGE

1) Do you have any supplemental prescription drug coverage under your policy or another family member?

YES ☐ **NO** ☐ (If **NO,** go to **SECTION D**)

If **YES**, what is your relationship to the policy holder? ☐ Self ☐ Family Member ☐ Both

2) What type of policy is your supplemental drug coverage?

☐ TRICARE ☐ MEDIGAP ☐ State Pharmaceutical Assistance Program (SPAP) ☐ OTHER

Please print below the name, and address of the insurance company providing your prescription drug coverage:

NAME

ADDRESS

ADDRESS

CITY STATE ZIP

POLICY NUMBER

DATE COVERAGE BEGAN (M M – D D – Y Y Y Y)

Please use your insurance card to provide the following information if available:

Rx GROUP

Rx PCN

MEMBER ID

Rx BIN

(CONTINUED ON NEXT PAGE)

SECTION D - MORE INFORMATION ABOUT YOU

1) Are **YOU** receiving **Black Lung** Benefits? **YES** ☐ **NO** ☐
2) Are **YOU** receiving **Workers' Compensation** benefits? **YES** ☐ **NO** ☐
3) Are **YOU** receiving treatment for an injury or illness which another party could be held liable or could be covered under no-fault or auto insurance? **YES** ☐ **NO** ☐

If **YOU** answered **YES** to any questions in this section, go to **SECTION E**
If **YOU** answered **NO** to all of these questions, sign below and return this form.

Your Signature

AREA CODE **PHONE NUMBER**

SECTION E - MORE INFORMATION ABOUT YOUR BENEFITS

1) If **YOU** are getting **Black Lung** (Coal Miner's) Medical Benefits, print the date the benefits began.

M M – D D – Y Y Y Y

2) If **YOU** are now receiving any medical services related to an illness or injury which occured on the job, for which **YOU** have or will file a **Workers' Compensation** claim, print the date the illness or injury.

M M – D D – Y Y Y Y

Please provide information about the employer, insurance carrier, and attorney in the spaces below:

EMPLOYER NAME

ADDRESS

ADDRESS

CITY STATE ZIP

NAME OF INSURANCE CARRIER

ADDRESS

ADDRESS

CITY STATE ZIP

POLICY or CLAIM NUMBER

NAME OF ATTORNEY (If Applicable)

ADDRESS

ADDRESS

CITY STATE ZIP

BRIEF DESCRIPTION OF ILLNESS OR INJURY

PROOF 050713

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SECTION E - MORE INFORMATION ABOUT YOUR BENEFITS, CONTINUED

3) If **YOU** are now getting any treatment for an illness or injury for which another party could be held liable, please print the date of illness or injury: ___ — ___ — ____
M M D D Y Y Y Y

NAME OF INSURANCE CARRIER

ADDRESS

ADDRESS

CITY STATE ZIP

POLICY or CLAIM NUMBER

NAME OF ATTORNEY (If Applicable)

ADDRESS

ADDRESS

CITY STATE ZIP

BRIEF DESCRIPTION OF ILLNESS OR INJURY

4) If **YOU** are now getting any treatment for an illness or injury which could be covered under **no-fault** or **automobile insurance**, print the date the of illness or injury: ___ — ___ — ____
M M D D Y Y Y Y

NAME OF INSURANCE CARRIER

ADDRESS

ADDRESS

CITY STATE ZIP

POLICY or CLAIM NUMBER

NAME OF ATTORNEY (If Applicable)

ADDRESS

ADDRESS

CITY STATE ZIP

BRIEF DESCRIPTION OF ILLNESS OR INJURY

Your Signature

AREA CODE **PHONE NUMBER**

PROOF 050713

Appendix C – Issues for Other Entities Providing Prescription Drug Coverage

As provided in 42 CFR 423.464(f), Part D plans must permit SPAPs and entities providing other prescription drug coverage to coordinate benefits with them. Examples of entities providing other prescription drug coverage include SPAPs, Medicaid programs, group health plans, Federal Employee Health Benefits Program (FEHBP) plans, military coverage, Indian Health Service coverage, federally qualified health centers (FQHCs), and rural health centers (RHCs). In this appendix, we discuss COB issues applicable to some of these entities.

State Pharmaceutical Assistance Programs (SPAPs)

Qualified SPAPs are unique among other payers because any payments supplementing the benefits available under Part D coverage before a beneficiary reaches the annual out-of-pocket limit made on their enrollees' behalf count toward TrOOP. We expect that qualified SPAPs will share enrollment files with CMS through the data sharing arrangements outlined in section 30.1. Although SPAP wrap-around coverage automatically counts toward TrOOP – and some programs have questioned the need for SPAPs to participate in our COB and TrOOP facilitation processes – there are benefits to participation in our COB process as other payers. For example, as part of our enrollment file sharing with SPAPs, we provide SPAPs with certain information fields (for example, low-income subsidy status and details) that they will need to effectively wrap-around Part D coverage on behalf of their Part D enrollees. In addition, as noted above, by making their claim payments a matter of record with the Part D plans, SPAPs provide the means for Part D plans to execute reimbursement of erroneous payments, such as those that may occur in reimbursing cost sharing incurred by low-income subsidy eligible enrollees between the date of their eligibility and the time the subsidy has been programmed by the Part D plan. Most importantly, participation in the TrOOP facilitation process allows the beneficiary's multiple benefits to process seamlessly at the point of sale, even if they do not present all of their ID cards.

Exchanging Historical and Ongoing Claims Data

As mentioned in section 50.12, "Sharing of Claims Data" of this document, we cannot require data exchanges between Part D plans and the States, except as required for COB purposes. However, we strongly encourage plans to independently share historical and ongoing data on these shared enrollees with SPAPs, provided such disclosure is consistent with the requirements of the HIPAA Privacy Rule. Drug history exchanges between states and plans are discussed further in the section 50.12.

Coordinating Payment

As provided in these guidelines, SPAPs may choose to coordinate their benefits with Part D plans using a variety of approaches. With the exception of the risk-based approach, all Part D plans are required to coordinate with the SPAP. As indicated in the prior section discussing the non-risk approach, CMS will take compliance action against all plans that do not comply with the non-risk requirement. If a plan is out of compliance with this requirement, CMS will not disqualify a state program from its qualified SPAP status. SPAPs will not be viewed as discriminating based on Part D plan's non-compliance because CMS believes the plan, by failing to adhere to this COB requirement, has effectuated the discrimination. We will require states to collect an attestation from the plan that it does not want to participate in the non-risk approach. States will submit this attestation to CMS so that CMS may work with the plans to comply with this COB requirement. Plans will also be required to provide information to its beneficiaries that it is not participating in the state's program.

In addition to the lump sum scenarios mentioned in Section 50.7 of this chapter, SPAPs may provide their own wrap-around benefit at the point-of-sale, or solicit a plan or processor who agrees to administer their wrap-around benefit for them. The plan or processor (who may or may not be a Part D plan sponsor) will administer their SPAP wrap-around benefit. This organization will agree to administer the SPAP benefit to all Part D beneficiaries that qualify for the SPAP benefit regardless of what Part D plan in which the beneficiary is enrolled. As the administrator of the benefit, SPAPs will most likely require these organizations to:

- Process secondary claims using the NCPDP V. 5.1 electronic claims format.
- Require COB segment on the secondary claim.
- Provide coverage of drugs on the State's formulary.
- Provide coverage of drugs at SPAP network pharmacies.
- Administer rebates applicable to the SPAP wrap benefit.

Enrollment

Certain SPAPs may have the authority to enroll their members directly into Part D plans if using an enrollment methodology expressly approved by CMS, and have expressed a desire to be allowed to use a standard electronic file format to complete the enrollment process. While Part D plans will not be required to accept a standard electronic file directly from an SPAP, we encourage them to negotiate with SPAPs on this point so as to facilitate a streamlined enrollment process.

Medicaid

Beginning January 1, 2006, Medicaid can no longer receive Federal Financial Participation (FFP) for drugs covered under Part D that are provided to full benefit dual eligibles. State Medicaid programs will continue to have the option of providing Medicaid coverage of drugs listed under section 1927(d)(2) of the Social Security Act, which the MMA excludes from the definition of coverage under Part D drugs. To the extent that Medicaid covers those excluded drugs, the state can receive FFP for that coverage. However, coverage of non-Part D drugs by State Medicaid programs will not count toward a beneficiary's TrOOP balance.

Drug coverage— We understand that many Medicaid programs may wish to provide coverage for non-Part D drugs to provide continuity of coverage to dual eligible Part D enrollees. To that end, Part D plans may wish to develop a process whereby the pharmacy is informed that Medicaid is a payer only if a claim is denied as a non-Part D drug and there are no other secondary/tertiary payers that may pay the claim. As of August 2006, Part D plans are required to implement reject messaging that will allow pharmacies to identify claims for excluded Part D drugs that can be billed to the state.

Data exchange— As discussed previously in Section 50.12 of this chapter, we do not have the authority to require data exchanges between Part D plans and the States, except as required for COB purposes. However, we strongly encourage Part D plans to independently share historical and ongoing data on these shared enrollees with State Medicaid agencies, provided such disclosure is consistent with the requirements of the HIPAA Privacy Rule. We believe claims data exchanges will be mutually beneficial to States and Part D plans as they structure their benefits.

Veterans Administration Coverage

VA benefits – including prescription drug coverage – are separate and distinct from benefits provided under Part D. By law, VA cannot bill Medicare. In other words, coordination of benefits between Part D and VA benefits is not possible. While a beneficiary may be eligible to receive VA prescription drug benefits and enroll in a Part D plan, he or she cannot use both benefits for a single prescription. VA prescriptions generally must be written by a VA physician and can only be filled in a VA facility or through VA's Consolidated Mail Outpatient Pharmacy (CMOP) operations. VA does not fill prescriptions for Part D plans. Since VA and Part D benefits are separate and distinct, a veteran's payment of a VA medication copayment does not count toward his or her gross covered drug costs or TrOOP expenditures under his or her Part D benefit.

Given the fact that VA prescription drug coverage is creditable coverage, beneficiaries will not face a penalty if they delay enrollment in a Part D plan. However, some beneficiaries who receive less than full VA prescription drug benefits may benefit from enrollment in a Part D plan – particularly if they are eligible for the low-income subsidy.

TRICARE

TRICARE for Life pays secondary to Medicare to the extent that a benefit is payable by both Medicare and TRICARE. TRICARE for Life's pharmacy benefit wraps around Medicare Part D and will pay any beneficiary cost-sharing remaining – up through the cost-sharing that beneficiary would have had otherwise paid under TRICARE – but only if a beneficiary is enrolled in a Part D plan, the drug is a covered Part D drug, the covered Part D drug is also covered by TRICARE, and the drug is obtained at a pharmacy participating in both the Part D plan's and TRICARE's network.

Given the fact that TRICARE for Life is creditable coverage, beneficiaries will not face a penalty if they delay enrollment in a Part D plan. However, some beneficiaries who receive TRICARE for Life benefits may benefit from enrollment in a Part D plan – particularly if

they are eligible for the low-income subsidy. To the extent that a beneficiary is enrolled in both TRICARE for Life and a Part D plan, information about that beneficiary's TRICARE coverage should be captured and maintained by the COB Contractor, and available to Part D plans as part of the COB process, through the MARx system. Any wraparound payments made by TRICARE for covered Part D drugs will count toward a Part D enrollee's gross covered drug costs but not toward TrOOP because TRICARE is a government-funded health program and, as such, a TrOOP-excluded payer.

Indian Health Service (IHS)/Tribal Health Coverage

The Indian health care system, consisting of tribal, urban, and federally operated Indian Health Service (IHS) programs, delivers a spectrum of clinical and preventive health services to its beneficiaries, via a network of hospitals, clinics, and other entities. Section 42 CFR 423.464(f) implementing the Part D coordination of benefit (COB) requirements requires plans to coordinate benefits with the IHS and providers of other prescription drug coverage. Tribal health coverage is recognized by CMS as a provider of other prescription drug coverage.

In most cases, supplemental coverage by I/T/U facilities will not be considered TrOOP eligible because these entities will fall under our definition of "government-funded health program," in 42 CFR 423.100. However, plans should be aware that some tribes, when providing other prescription drug coverage, may be independent entities that use only non-Federal subsidized funding to pay secondary coverage for all medical services, including Part D drugs. This being the case, the secondary coverage may be TrOOP-eligible.

Although assistance with Part D cost-sharing by pharmacies operated by the Indian Health Service, Indian tribes or tribal organization, or urban Indian organizations (also known collectively as I/T/U pharmacies) may not count as incurred costs toward meeting the out-of-pocket threshold at which catastrophic coverage under the Part D benefit begins, neither the MMA nor its implementing regulations prohibit I/T/U facilities from assisting with cost-sharing or subsidizing of premiums. In fact, by custom and regulation, American Indian/Alaska Native (AI/AN) beneficiaries cannot be charged any cost-sharing, meaning that I/T/U facilities must waive any co-payments or deductibles that would have been applied by a Part D plan. Our regulations require all Part D sponsors to offer network contracts to all I/T/U pharmacies operating in their service area and, in addition, will have to demonstrate to CMS that they provide convenient access to I/T/U pharmacies for AI/ANs. Thus, COB with the IHS and tribes is inextricably tied to pharmacy network contracting with I/T/U pharmacies. I/T/U pharmacies may submit claims to Part D plans electronically (or via paper claims, to the extent that some of the more remote I/T/U sites lack electronic capability). There does not exist any capability under the current NCPDP Telecommunication Standard Implementation Guide for I/T/U pharmacies that are not TrOOP-eligible to indicate the subsidization by IHS or tribes of any applicable beneficiary cost-sharing so that such subsidies are not applied to the beneficiary's TrOOP balance. We recommend that plans set up logic in their systems so that all claims from network I/T/U pharmacies are flagged and any applicable beneficiary cost-sharing is not added to the beneficiary's TrOOP amount. For cases in which tribal organizations using tribal-only money qualify as TrOOP-eligible payers, Part D plans must set up manual processes to receive this information and to adjust TrOOP calculations accordingly.

If a tribal member was initially unable to receive Part D benefits through the Part D plan, the tribe may have stepped in to pay for the AI/AN Medicare eligible's Part D prescription drugs, utilizing a non-Federal source of funds, in lieu of a Part D plan's primary coverage. In such cases, tribes are entitled to seek compensation from the Part D plan once enrollment is confirmed. Consistent with our COB requirements, plans will be required to reimburse tribes when the tribe has paid primary, just like any other provider of prescription drug coverage.

Safety-Net Providers

A majority of Medicare beneficiaries served by safety-net provider organizations have limited incomes. These safety-net provider typically include Federal, State, and locally supported community health centers (CHCs) or clinics, many of which are deemed Federally Qualified Health Centers (FQHCs), public hospital systems, and local health departments. In some communities they also include mission-driven teaching hospitals, community hospitals and ambulatory care clinics (which are often located in central city areas or serve as the sole provider of health care in the community). Rural health clinics (RHCs), small rural hospitals, critical access hospitals (CAHs), clinics that receive Ryan White HIV/AIDS grant funding, and nurse managed clinics also constitute key components of the safety net.

An estimated 12,000 safety-net providers participate in the Health Resources and Services Administration's (HRSA) 340B Drug Pricing Program, which allows them to buy their prescription drugs at significantly discounted prices. Participation in the 340B Program can enable pharmacies to provide prescriptions to their patients at lower-than-market price. Because many safety-net providers acquire their prescription drugs through Federal purchasing programs such as the 340B Drug Pricing Program, access to prescription drugs and pharmacy services may be limited to their own patients and not to the public at large. Such "closed pharmacies" may therefore not be open to the general public. For this reason, safety-net pharmacies are typically smaller and less visible to the public than retail pharmacies.

Part D sponsors are not required to contract with safety-net providers. However, we created an incentive for Part D plans to contract with certain safety-net providers – FQHCs and RHCs – by allowing them to count these pharmacies toward their retail pharmacy networks. COB between Part D plans and safety-net providers is therefore inextricably tied to pharmacy network contracting with safety net pharmacies.

The MMA added a new exception to the anti-kickback statute under which pharmacies are permitted to waive or reduce cost-sharing amounts provided they do so in an unadvertised, non-routine manner after determining that the beneficiary in question is financially needy or after failing to collect the cost-sharing amount despite reasonable efforts. In addition, a pharmacy may waive or reduce a beneficiary's Part D cost-sharing without regard to these standards for Part D enrollees eligible for the low-income subsidy provided the pharmacy does not advertise that the waivers or reductions of cost-sharing reductions are available. In other words, for low-income subsidy recipients only, pharmacies do not need to ensure that the waiver or cost-sharing reduction is non-routine and provided only after ascertaining financial need. However, they cannot in any way advertise the provision of the waiver or cost-sharing reduction. We have previously advised that, provided pharmacies follow these rules, such waivers or reductions of Part D cost-sharing by pharmacies would count toward a beneficiary's TrOOP.

However, we clarify that, to the extent that the party paying for cost-sharing on behalf of a Part D enrollee is a group health plan, insurance, government-funded health program, or party to a third party payment arrangement with an obligation to pay for covered Part D drugs, that party's payment will not count toward TrOOP. Thus, payments made for beneficiary cost-sharing by any entity – including a safety-net pharmacy– that has an obligation to pay for covered Part D drugs on behalf of Part D enrollees, or which voluntarily elects to use public funds (from Federal, State, and/or local government funding sources) for that purpose, will not count toward that beneficiary's TrOOP expenditures.

To the extent that safety-net pharmacies are government-funded health programs or other TrOOP-ineligible payers waive or reduce any applicable Part D enrollee cost-sharing after payment of a claim by the Part D plan, that claim (whether electronic or paper, to the extent some of the more remote safety net pharmacies lack electronic capability), must be flagged such that any applicable beneficiary cost-sharing that is waived or reduced by the pharmacy is not added to a beneficiary's TrOOP balance. Currently, there does not exist any capability under the NCPDP 5.1 transaction set for safety-net pharmacies to indicate a pharmacy's waiver or reduction of any applicable beneficiary cost-sharing so that such subsidies are not applied to the beneficiary's TrOOP balance. We recommend that plans set up manual processes with safety-net pharmacies in their network in order to accurately maintain beneficiary TrOOP balances.

Patient Assistance Programs (PAPs)

Pharmaceutical manufacturers and other entities sponsor a number of patient assistance programs (PAPs) to provide financial assistance or free product (through in kind product donations) to low income patients – particularly those with incomes below 200 percent of the federal poverty level (FPL) – with no or insufficient prescription drug coverage.

Regardless of whether a PAP is a bona fide charity – and unless the PAP is a group health plan, insurance or otherwise, or other third party payment arrangement – any drug payment a PAP makes on behalf of a Part D enrollee will count toward a beneficiary's TrOOP balance. In addition, we will allow PAPs the option of providing assistance for covered Part D drugs on behalf of Part D enrollees outside the Part D benefit. Under this option, a PAP would operate outside of the Part D benefit, and any assistance it provides to a Part D enrollee for drugs that would have been covered under his or her Part D plan would not count as an incurred cost that would be applied toward the enrollee's TrOOP balance or total drug spend. In other words, when operating outside the Part D benefit (and beginning at the point at which a beneficiary's assistance under a PAP is effective), a claim for the drug for which a PAP had provided assistance would never be submitted to a beneficiary's Part D plan.

Operating outside the Part D benefit does not preclude a PAP sponsor from requiring its enrollees – including those enrolled in a Part D plan – from paying a nominal copayment when they fill a prescription for a covered Part D drug for which they provide assistance. We believe that any copayments assessed by PAPs operating outside the Part D benefit should be nominal, since only nominal beneficiary cost-sharing is consistent with the concept of operating outside Part D. Moreover, given that copayments are typically assessed for purposes of minimizing drug overutilization, the assessment of anything but nominal cost-

sharing by PAPs is seemingly inconsistent with the mission of a charitable organization structured to provide assistance with prescription drug costs to low-income patients.

Although PAP payments made for those covered Part D drugs outside the benefit may never count toward enrollees' TrOOP or total drug spend balances, we clarify that any nominal PAP copayment amounts paid by Part D enrollees will be aggregated to their TrOOP and total drug spend balances, provided the enrollees take responsibility for submitting the appropriate documentation to their plan. It will not be permissible, however, for beneficiary payments structured as administrative fees or premiums to be aggregated to Part D TrOOP and total drug spend balances, as these types of beneficiary out-of-pocket expenditures do not meet the definition of "incurred costs" at 42 CFR 423.100.

Enrollee submission of this documentation is necessary because a PAP operating outside the Part D benefit should never submit a claim for assistance provided for a covered Part D drug to a Part D enrollee's Part D plan. Consistent with our guidance on claims processing, plans should process these enrollee-submitted claims in the order in which they are received, not based on date of service.

As noted elsewhere in this chapter, in order to facilitate implementation of this policy, plans should establish processes and clear instructions for enrollee paper claim submissions such that they can distinguish between claims submitted for : (1) out-of-network coverage; (2) adjustment to TrOOP balances based on wraparound payments by supplemental payers not previously submitted to the plan; (3) documentation submitted for a purchase made via a discount card or other special cash discount outside the Part D benefit in any applicable deductible or coverage gap phase of the benefit; and (4) documentation submitted for a copayment assessed by a PAP sponsor operating outside the Part D benefit for assistance provided with covered Part D drug costs. We plan to develop and share with plans model paper claims submission forms they can use or revise for these purposes.

The choice of whether to operate inside or outside the Part D benefit would be entirely at each individual PAP's discretion, although the PAP would still need to comply with the Federal fraud and abuse statutes. We note that the issue of establishing criteria for applicability of PAP assistance remains up to each individual PAP. PAPs have discretion to decide at what point financial burden triggers PAP assistance – for example, a set income level or an asset test or a ratio of drug cost to income or assets. [We note, however, that a criterion of being uninsured would be problematic because we do not consider a Part D enrollee in the benefit's coverage gap to be "uninsured" for purposes of a PAP's determination of financial need. Although a Part D enrollee may be required to pay 100 percent cost-sharing until he or she has reached the out-of-pocket threshold in TrOOP expenditures, that individual continues to have coverage under the Part D plan given his or her access to negotiated prices and continued payment of premiums.]

Once a beneficiary satisfies a PAP's eligibility criteria, however, we believe the PAP should provide assistance through the end of the year. If, for budgetary reasons, a PAP declines to commit to providing assistance through the year, the PAP may decide to limit the amount of drug it will provide to any PAP enrollee. If a PAP decides to set such a cap, such cap should apply uniformly to all PAP enrollees - and not just to Medicare beneficiaries - and should be determined in a manner that is not directly or indirectly related to other drug expenditures by Part D enrollees. PAPs must not employ a cap to terminate PAP assistance in a manner

designed to correlate with when the beneficiary's other drug expenditures might suffice to trigger catastrophic coverage under Part D or otherwise as a proxy for when Federal reimbursement would be available for the beneficiary's drugs. (Please refer to the examples at the end of this PAP section regarding how TrOOP and total Part D drug spend are affected depending on when enrollment in a capped program takes place and whether an enrollee surpasses the cap in a given coverage year).

The option of operating outside the Part D benefit, with or without the assessment of nominal enrollee copayments for assistance provided, will allow PAP sponsors to continue providing needed assistance to financially needy beneficiaries – those whose incomes are too high to qualify for the low-income subsidy, but whose incomes are low enough that out-of-pocket costs on drugs are still burdensome – while allowing the individual PAPs flexibility to determine the form of their donations and, if operated with sufficient safeguards, to use existing PAP programs to assist needy beneficiaries. We note, however, that we will be monitoring the impact of this guidance and reserve the right to revise it for future plan contract years.

The most effective – and, ultimately, for the beneficiary, the safest – way for PAPs to operate outside the Part D benefit would involve front-end data exchanges with CMS through the use of PAP-specific trading partner agreements, which we will provide further information about in forthcoming guidance. General information about eligibility file exchange with supplemental payers and other entities is provided in Section 30.1 of this chapter. To the extent that a PAP exchanges eligibility files with us, we will be able to flag it as a non-TrOOP eligible payer for the particular Part D drugs it provides Part D enrollees at no cost. This information would therefore be available to plans through the TrOOP facilitation process, and plans would be alerted to the fact that they must follow up with the PAP to identify the prescription drug provided outside the benefit. This, in turn, would allow plans to set their systems to recognize that drug as part of a patient’s profile, while setting systems edits to prevent any payment for that prescription. As a result, a beneficiary will be able to obtain free product through the PAP without affecting either TrOOP or total drug spend amounts on plan PDE records. As a result of the data exchange process, the PAP will also receive information regarding its enrollees’ Part D enrollment status.

To address safety concerns associated with prescription drugs provided outside the Part D benefits, the front-end data exchange process will enable, as described above, plans to follow-up with PAPs to identify those Part D drugs an enrollee is receiving outside the Part D benefit. This will facilitate plans’ provision of required drug utilization review and, if applicable, medication therapy management program activities. If a PAP did not exchange information with CMS in the manner outlined above, such information would remain unknown to the plan, which could potentially lead to quality of care issues. For these reasons, we strongly encourage PAPs wishing to operate outside the Part D benefit participate in this process. Alternatively, a PAP could provide its enrollees with a notice they could provide to their Part D plans indicating that they are receiving one or more drug products from that PAP.

PAP sponsors, whether operating inside or outside the Part D benefit, remain responsible for complying with relevant fraud and abuse laws, including the anti-kickback statute. Liability under the anti-kickback statute requires a case-by-case analysis of the particular facts and circumstances, including the intent of the parties. However, to the extent that PAPs choose to

operate within the Part D benefit, generally, the least problematic way of providing assistance with the costs of covered Part D drugs to Part D enrollees is through support of independent PAPs operated by bona fide public charities without regard to donor interests. Properly structured, these programs can offer an alternative that reduces the risk of fraud or abuse. Among other things, the charity must make an independent determination of patient need, and the patient's receipt of assistance may not depend directly or indirectly on the patient's use of any particular product or supplier of drugs.

We have also received inquiries about the ability of PAPs to pay Part D premiums on behalf of enrollees or to provide free or discounted product through a coalition of manufacturers. Nothing in CMS rules and regulations prohibit such arrangements. We also note that organizations or entities offering patient assistance programs must comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. The HHS Office of the Inspector General (OIG) enforces Federal fraud and abuse statutes, and all questions regarding the compliance of specific arrangements with these statutes should be referred to the OIG.

Examples of Impact on TrOOP and Total Part D Drug Expenditures in Capped Patient Assistance Programs Where the PAP Operates Outside of Part D

Scenario 1: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning January 1, 2007. Mrs. Jones uses $2,500 worth of free Drug ABC in 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$0	$0

Scenario 2: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part D drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1265	$515 ($265 deductible plus 25% coinsurance on $1000)

Scenario 3: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP Y. PAP Y imposes nominal cost-sharing of $5 for each prescription filled, and finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning March 1, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and March 1, 2007 and purchases no additional covered Part D drugs. She then uses $2,500 worth of free Drug ABC between March 1 and December 31, 2007. PAP Y imposes $50 of nominal beneficiary cost-sharing ($5 for each of 10 fills) between March 1 and December 31, 2007. Mrs. Jones submits the appropriate documentation to her PDP for all the nominal copayments assessed by the plan so that they may be aggregated to her TrOOP and total drug spend balances.

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$2500	$1315 ($1265 of total drug spend prior to March 1, 2007, plus $50 in nominal PAP copayments)	$565 ($265 deductible, plus 25% coinsurance on $1000, plus $50 in nominal PAP copayments)

Scenario 4: Mrs. Jones enrolls in a PDP with a defined standard benefit with an effective coverage date of January 1, 2007. Mrs. Jones applies for assistance with her drug costs with PAP X. PAP X does not impose any nominal beneficiary cost-sharing, but finds that she meets the financial need criteria to receive $5,000 worth of free Drug ABC beginning May 15, 2007. Mrs. Jones purchases $1,265 worth of Drug ABC between January 1 and May 15, 2007, and she purchases no additional covered Part D drugs. She then uses $5,000 worth of free Drug ABC between May 15 and November 1, 2007. Since she has reached PAP X's spending cap for Drug ABC, she begins to use her Part D benefit again for Drug ABC beginning November 1, 2007.

She purchases $1,000 worth of Drug ABC between November 1 and December 31, 2007 (during this time period, she is in the coverage gap of the standard defined benefit given use of other covered Part D drugs throughout the year).

Donated Product	Dollar Value of Donated Product	Dollar Value of Donated Product Utilized	Impact on Total Drug Spend	Impact on TrOOP
ABC	$5000	$5000	$2265	$1515 ($265 deductible plus 25% coinsurance on 1st $1000 plus $1000 in coverage gap)

Personal Health Savings Vehicles

In our final regulations, we indicated that Health Savings Accounts (HSAs), Flexible Spending Accounts (FSAs), and Archer Medicare Savings Accounts (MSAs) are not group health plans for TrOOP purposes, and that distributions from these personal health savings vehicles will count as incurred costs for the purposes of TrOOP accounting. Thus, information about these accounts need not be reported to CMS. However, if any of these accounts is set up to pay benefits at the point-of-sale, and wishes to be included in the automated payer data exchange provided by the TrOOP Facilitation Contractor, the administrators of such accounts would need to exchange eligibility files with CMS and be included in the COB files provided by CMS. Alternatively, account administrators may require beneficiaries to submit paper claims after the POS transaction and can then submit those claims to the TrOOP Facilitation Contractor in batch form. The TrOOP Facilitation Contractor will create an NCPDP N1 transaction based on that batched claims data and will send it back to the beneficiary's Part D plan for accurate TrOOP recalculation.

Health Reimbursement Arrangements (HRAs), however, generally are considered group health plans for purposes of Part D, and distributions from these accounts will not count toward TrOOP. HRAs are therefore group health plans subject to all the requirements that apply to other payers providing prescription drug coverage. HRA administrators will have the option of entering into data sharing agreements offered by CMS, or they can submit batched claims data to the TrOOP Facilitation Contractor after the POS transaction. This will help supplement the information about other payers that beneficiaries must relay to their Part D plans and aid in the accurate calculation of TrOOP.

AIDS Drug Assistance Programs (ADAP)

AIDS Drug Assistance Programs (ADAPs), which are funded under the Ryan White CARE Act, are an integral component of the safety-net for HIV/AIDS patients because they fill coverage gaps in public and private insurance for critical HIV/AIDS drug treatments. Although assistance with Part D cost-sharing by ADAPs may not count as incurred costs toward meeting the out-of-pocket threshold at which catastrophic coverage under the Part D benefit begins, neither the MMA nor its implementing regulations prohibit ADAPs from assisting with cost-sharing or subsidizing of premiums.

To the extent that ADAPs want to be set up to pay benefits at the point-of-sale and wish to be included in the automated payer data exchange provided by the COB Contractor, they will need to exchange eligibility files with CMS and be included in the COB files provided by CMS. The advantage to this approach is that claims will be automatically adjudicated at point-of-sale (POS). Alternatively, ADAPs may require beneficiaries to submit paper claims after the POS transaction and can then submit those claims to the TrOOP Facilitation Contractor in batch form. The TrOOP Facilitation Contractor will create an NCPDP N1 transaction based on that batched claims data and will send it back to the beneficiary's Part D plan for accurate TrOOP recalculation.

Medicare Part B Coverage

We acknowledge that there are numerous complexities for Part D plans in distinguishing between drugs covered under Parts B and D of Medicare, as well as with wrapping around existing drug coverage under Part B. As provided in section 1860D–2(e)(2)(B) of the Act, Part D plans may not cover under Part D any drug that would otherwise be considered a Part D drug but which, as so prescribed and dispensed or administered to that individual, payment would be available under Parts A or B of Medicare. Despite the complexities involved in distinguishing when a particular drug is a Part B or a Part D drug, we believe Part D plans can best wrap around existing Part B coverage by understanding the scope of the definition of a covered Part D drug, and becoming familiar with the general categories of Part B covered drugs. To facilitate this understanding we have provided extensive guidance regarding Part B versus Part D coverage. This guidance is located on our website at: http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf . Part B versus Part D coverage will also be discussed in Chapter 6 of this manual.

Appendix D – Part D Requirements Waived for Programs of All-inclusive Care for the Elderly (PACE Organizations)

PACE is a comprehensive, coordinated model of care designed to meet the needs of frail elders. There are several key differences between the way in which PACE organizations (POs) provide the Part D benefit and how it is provided by other Part D plans.

Tracking of TrOOP

- Dual Eligible Beneficiaries:
  CMS fully subsidizes dual eligible individuals' Part D coverage in PACE organizations. Therefore, consistent with PACE rules, there is no beneficiary out-of-pocket expense, which eliminates the applicability of TrOOP for these beneficiaries.

- Beneficiaries Eligible for Only Medicare:
  PACE beneficiaries who are only Medicare eligible pay a supplemental premium based on the anticipated cost-sharing covered by the PACE plan. As a result, for these beneficiaries TrOOP does not apply.

Accessing Covered Part D Drugs

For the most part, POs fully coordinate their participants' access to covered Part D drugs, providing prescriptions directly to the participant. As a result, most POs are not set up for real-time, on-line prescription drug claims processing and neither have nor report 4Rx data to CMS.

Transferring Data When a Beneficiary Changes Plans

When a beneficiary disenrolls from a PO and re-enrolls in another Part D plan at any time during the coverage year, the PO is required to transfer the TrOOP balance (if any) and the gross covered drug spending to new plan of record to permit the correct placement of the beneficiary in the benefit.

CMS will continue to develop guidance to further clarify the applicability of the COB requirements to the POs.