DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR BENEFICIARY CHOICES

June 22, 2006

Memorandum To: All Part D plans

Subject: 2007 Draft COB Guidelines

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

Please find attached the 2007 draft Coordination of Benefit (COB) guidelines for review and comment. The draft 2007 COB Guidance incorporates a number of changes to clarify existing policy, describe updated systems and processes related to COB, and explain new and proposed policy and requirements.

In order to identify changes from the 2006 guidelines, the draft is posted as a red-line version. Comments may be submitted on this draft until COB July 14, 2006 at drugbenefitimpll@cms.hhs.gov . Please include *COB Guidelines* in the subject line.

A summary of these changes follows.

- A description of both the new and modified COB enrollment file sharing programs for the exchange of Part D information.
- A more detailed discussion of the COB Contractor's role in Part D and systems connectivity requirements.
- Described upcoming enhancements to the E1 transactions.
- Inclusion of two potential new uses for the N1 transaction for information exchange.
- Description of the expected revisions to the enrollment transaction process to require 4Rx data on all enrollment transactions.
- Expanded discussion of the required COB survey of beneficiaries and incorporated a copy of the CMS-developed electronic survey.
- Required follow-up when a plan receives an N1, but has no supplemental payer information on file.
- Encouraged plans to use the optional fields in their electronic transactions to assist secondary payers in coordinating benefits.
- Added language regarding an enrollee's ability to purchase a covered Part D drug without using their Part D benefit or a supplemental payer's coverage if they can receive a better cash price.
- Included requirements for the use of new standardized claims messaging.
- Clarified that a plan cannot disenroll a beneficiary if a plan has failed to coordinate premium payments with other payers.

- Reiterated the requirement that all plans adopt a non-risk-based lump sum approach with SPAPs. Further, if they do not, they will be out of compliance and states will not be considered discriminating if the state has to inform their beneficiaries that a plan is not participating.
- Added language concerning a SPAP use of a single processor process.
- Incorporated a new description of the current process for transferring TrOOP balance information when a beneficiary changes plans and a potential automated approach for 2007.
- Included proposed new requirements for a special transition and COB process for retroactive enrollment situations, including retroactive Medicaid eligibility.
- Expanded the discussion of MSP requirements when WC Medicare set-asides are involved.
- Clarified plan requirements for executing a business associate agreement with the TrOOP Facilitation Contractor.
- Included descriptions of the new payment reconciliation requirements and processes, including situations in which re-adjudication is required in lieu of pharmacy reprocessing.
- Reiterated the claims filing timeframes requirements.
- Expanded the discussion of the Medicaid drug history file exchange, providing details on how set up a file exchange.
- Clarified that VA benefits are separate and distinct from benefits provided under Part D, and that COB between Part D and VA benefits is not possible.
- Revised language regarding COB with TRICARE.
- Expanded discussion of COB with IHS and Tribes, including new language on plan requirements to reimburse tribes when they have paid primary in lieu of a Part D plan's primary coverage.
- Included revised language regarding COB and PAPs, incorporating existing guidance on PAPs operating outside the Part D benefit.

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Draft 2007 Part D Coordination of Benefits Guidance
June 2006

I. Overview

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This document provides guidance to Part D sponsors regarding our requirements and procedures for coordination of benefits (COB) between Part D plans and 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.

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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 – 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

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by CMS are used in part for that purpose), but they could charge for activities such as the exchange of claims data.

Although this document is meant primarily as guidance 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 will work. In Appendix B, 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), and Medicare Part B. Further guidance on systems requirements and technical details involved in the COB process have been issued in other communications.

II. 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 below in section II.D), we support the tracking and calculation of enrollees' TrOOP balances by Part D plans.

A. 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 (COBC) to collect information on beneficiaries' other coverage primarily through the use of data sharing agreements. Those known as Voluntary Data Sharing Agreements (VDSAs) and Coordination of Benefits Agreements (COBAs) already existed and 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 COBC a file of its enrollees. For Part D purposes, the COBC: 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

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information updates; and 3) transmits the matches/updates to the Medicare Beneficiary Database (MBD). MBD sends this information to the TrOOP facilitator and the plan. Information about the format and business rules of the COB file to plans is contained in 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/.

B. Validation of Information about Other Payers

When a Part D plan or a beneficiary provides information to the COBC about other coverage, the COBC 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 COBC's role in Part D COB is to provide plans with assistance in identifying payments by other coverage and determining whether those payments count towards the beneficiary's TrOOP. Plans may use the data contained in the COB file to assist in making these determinations. Instructions on the use of the COB file are contained in the PCUG. However, Part D plans remain ultimately responsible for confirming the TrOOP-eligibility of other payer payments and applying these correctly to beneficiary TrOOP calculations (note that the other payer information conveyed to Part D plans may include a help desk number when provided by those payers). The COBC will provide a help desk functionality that, among other things, will help plans tie a particular RxBIN/PCN combination (the claims routing information) to a particular payer so that plans can follow up with that payer and make a final determination in their systems regarding the payer's TrOOP status.

C. 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 COBC 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 transaction to the pharmacy. The COBC calculates payer order based on MSP rules, relationship to

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CMS coordinates benefits with other payers 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 through the use of Voluntary Data Sharing Agreements (VDSAs) Coordination of Benefits Agreements (COBAs) and other processes. For Part D, the COB Contractor will compare the list of other payers' enrollees to the current population of Medicare enrollees, will capture and maintain this other payer information, and will transmit the information to the Medicare Beneficiary Database (MBD) on a daily basis. For more information about current Medicare COB processes, please consult: ¶
http://www.cms.hhs.gov/medicare/cob/. ¶
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We are modifying all current COB data collection and exchange activities specifically to account for prescription drug coverage enrollment information. Generally, we expect that other payers will enter into agreements to periodically submit an input file of enrollees to the COB contractor. In return, the payer will receive a response file from the COB contractor indicating which of its enrollees are Medicare Part D beneficiaries. The payer will send input files and get response files back in standard formats. We will provide the final record layouts, business rules other payers can use to program their internal systems, official data sharing agreements, and other relevant information about this process via separate technical guid … [1]

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The COB Contractor will provide plans with some assistance in determining a payer's TrOOP eligibility through this validation process. The contractor will crosswalk insurance type indicators to TrOOP eligibility. Further guidance on this will be forthcoming. Howeve … [2]

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policyholder, and type of supplemental insurance. Rules for using the payment order indicator are contained in the PCUG.

D. 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 Point of Sale (POS). To this end, Part D plans are required to utilize the existing current HIPPA-approved NCPDP standard 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.

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.

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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.

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 IV. L. Reconciling Payments).

Further enhancements to the E1 inquiry that will add data elements to the E1 response are planned for implementation prior to 2007. 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.

For instances in which Part D plan enrollees' secondary coverage is identified in advance by CMS systems (as described in section II.A), 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 COBC'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.

Additional uses of N1 transactions— CMS is currently working with the TrOOP Facilitation Contractor to explore two potential additional uses for N1 transactions that could facilitate Part D Plan activities related to coordination of benefits. These would permit:

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1. The exchange of drug-specific information between plans and patient assistance programs (PAPs) operating outside the Part D benefit to automate the communication of this information to the Part D plan, and

2. The exchange of information about drug purchases outside the plan's pharmacy contracts (e.g., through a discount card vendor) that count toward gross covered drug costs under the plan and TrOOP to ensure the accurate tracking of these balances by the Part D plan.

Results of this information from an expanded N1 transaction would allow plans to (1) incorporate information from PAPs into their drug utilization review programs and ensure any claims submitted for the drug(s) provided by PAPs outside the benefit are denied for payment, or (2) that covered prescription drug purchases made by the beneficiary using a non-Medicare discount card are added to a beneficiary's TrOOP balance.

CMS invites industry comment on these proposed new uses of the N1 in these contexts and solicits recommendations on any alternate means to automate these processes.

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. However, as discussed in section II.B, Part D plans remain ultimately responsible for confirming the TrOOP-eligibility of other payer payments and applying these correctly to beneficiary TrOOP calculations. 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.

E. 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

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TrOOP Facilitator to further support Part D Plan activities related to COB. Examples of these enhancements include:

- Additional uses for N1 transactions described in section II. D;
- 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, we expect the user fee will increased for 2007. Further guidance will be issued on how this increase will be handled with respect to plan bids.

III. Beneficiary Requirements

A. 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 and report that information to the COB Contractor for validation.

B. Using the 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, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicative claim reimbursements.

C. Submit 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 established by the plan so that their TrOOP balance and other accumulators can be updated timely.

IV. Part D Plan Requirements

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A. 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 that is submitted to the Medicare Beneficiary Database (MBD). If MBD accepts the 4Rx data, it is then sent to the TrOOP facilitation contractor to support the eligibility (E1) transaction from pharmacies, which is 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 no later than April 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.

B. 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 COBC so that it can be validated, captured, and maintained in MBD for COB purposes. Plans shall not transmit information about other coverage that the COBC has already applied to MBD and that the plan has already received in the COB file, but rather only change transactions. Anytime a Part D plan receives information concerning a change, this information should be sent electronically to the COBC within 30 days of receipt.

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

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beneficiaries, those who are deemed to have elected an MD-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 before October 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 several 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.

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.

C. Connectivity to CMS Systems

The COBC 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. The COBC pushes out updated information every Federal business day. 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 COBC.

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There is an electronic interface between Part D plans and the COBC 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 NDM 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 COBC on the transactions via a COB data report/file. The data provided by the COBC 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 COBC is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Part D plans should also be aware that, in the case of retroactive eligibility for the low-income subsidy, Part D plans are required to retroactively adjust claims and TrOOP balances based on prescription drug even (PDE) and claims records, as provided in 42 CFR 423.800(c).

Plans should also 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 shall use ECRS to send the information to CMS. Plans shall not use the enrollment update transaction to do so.

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.

D. 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 II.D of this document) that requires that Part D plans utilize the current HIPAA-approved NCPDP standard 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 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

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CMS will establish an electronic interface between Part D plans and the COB Contractor. The interface will allow Part D plans to submit post-enrollment transactions that change or add to currently-known COB information Part D plans will be updated on the status of these transactions as they move through the COB systems and will be informed on the determination made by the COB Contractor on the transactions via a COB data report/file. The data provided by the COB Contractor on supplemental payers and order of payment will be 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 COBC is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Part D plans should also be aware that, in the case of retroactive eligibility for the low-income subsidy, Part D plans will be required to retroactively adjust claims and TrOOP balances based on prescription drug even (PDE) and claims records, as provided in 42 CFR 423.800(c). CMS will provide installation and user guides, as well as installation software, to Part D plans as soon as possible, but no later than September 1, 2005.¶ ... [3]

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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 II. C) 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 IV.O. of this document for further detail on reconciling payments.)

Plan receives an N1, but has no 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 expects that plans will consider all components of their existing membership when developing the EOBs. Therefore, EOB should be appropriately tailored (e.g., for individuals eligible for LIS) to avoid misinforming the enrollees regarding their position in the benefit.

While this document is not meant to capture the TrOOP facilitation process in exhaustive detail, Appendix A contains more information, in flow chart format, about what this process entails. Additional information is available on the TrOOP Faciliation Contractor website at http://www.ndchealth.com/products_services/medicarePartD_introduction.htm. The NCPDP Implementation Guide is the official vehicle for establishing electronic processing rules. We also note that, as discussed in the preamble to our final rule (see page 4239) the Part D deductible may be paid by any payer, not only the beneficiary; it is not a requirement that it be paid out-of-pocket. If it is paid by a non-TrOOP-eligible payer, it does not count toward TrOOP, but it does get the enrollee into the initial coverage phase of the benefit. Therefore, Part D plans must count other payer paid

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amounts as satisfying the deductible, regardless of whether or not the entire amounts count toward TrOOP.

As mentioned in section II.B, CMS provides plans with assistance in determining a payer's TrOOP eligibility. Once the Part D plan gets an updated eligibility file, it becomes the Part D sponsor's responsibility to make this determination. The COB Contractor provides a help desk functionality that, among other things, helps plans tie a particular RxBIN/PCN combination to a particular payer so that plans can follow up with that payer and make a final determination in their systems regarding the payer's TrOOP status.

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 in the coverage gap (the plan's negotiated price). 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.

If an enrollee is able to receive a better cash price for a covered Part D drug at a network pharmacy (or at an out-of-network pharmacy, if such a purchase is consistent with the plan's out-of-network access rules) than the plan offers via its negotiated price, 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. This means that 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. Plans must accommodate the receipt of such information directly from enrollees and adjust total drug spend and TrOOP balances accordingly.

The applicability of a cash price for a covered Part D drug purchased without using a plan's Part D benefit card will be useful to an enrollee primarily during any deductible or coverage gap phases of the enrollee's benefit package, when he or she must pay 100 percent of the price of a drug. In addition, it is important to emphasize that an enrollee may apply a better cash price to his or her benefit for a covered Part D drug purchased only at: (1) a network pharmacy; or (2) at an out-of-network pharmacy, when such out-of-network access is consistent with his or her plan's out-of-network access policy.

We 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 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.

E. Standardized Claims Messaging

In 2007, CMS strongly encourages the rapid adoption and use of new standardized messaging procedures approved by the National Council for Prescription Drug Programs

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(NCPDP) in order for Part D plans to effectively 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. 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.

Part D Plans are likewise encouraged to promptly implement any additional new messaging similarly approved by the NCPDP Work Group at subsequent meetings to address other clarifying information needed to adjudicate a Part D claim and appropriately coordinate benefits in real time. CMS believes that the plan adoption of such messaging, until such time as alternative transactional coding is implemented in a new version of the HIPAA standard, is in the best interest of beneficiaries, pharmacies and payers.

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.

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.

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In accordance with CMS policy concerning "best available data", plans have the flexibility to develop their own procedures for determining whether best available information is sufficient to change or update their systems to reflect appropriate cost sharing levels for dual eligibles. However, when updated information on a beneficiary's low-income subsidy level is received, plans must re-adjudicate claims to reflect the correct cost sharing. (See the discussion in section IV. O distinguishing re-adjudication from reprocessing.) Plans are responsible for reimbursing or collecting amounts that result from the reprocessing of claims.

F. Accepting Payment of Premiums from Other Payers

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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.

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.

G. 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.

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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.

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

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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, especially in the first year when there is no historical cost or utilization data to rely upon. 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. Further guidance in these areas will be provided elsewhere.

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 (however, this is not required of other payers) to provide supplemental (cost sharing) benefits to their beneficiaries, as well as the following additional benefits:

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- 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
- Could work just as well for other payers, if desired.

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

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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. CMS will take compliance action against all plans that do not comply with this 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.

H. Claims Reconciliation Reports

Except for the non-risk-based lump sum with reconciliation approach described in section E, 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.

I. Transferring TrOOP Balance When 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.

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<#>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¶
<#>Could work just as well for other payers, if desired.¶
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The Non-Risk-Based Lump Sum Payment with Claims Reconciliation Approach¶
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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 be required to enter into arrangements to receive such subsidies and to apply the subsidy amounts to first dollar coverage of cost sharing for … [4]

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For 2006, the Plan-to-Plan Explanation of Benefits (EOB) Transfer Process was 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] 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 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.

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.

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

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

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.

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.

Until an automated process is implemented, plans will continue to use the alternative process for the transfer of EOB information that is described above with one proposed modification. Specifically, the transfer EOB in addition to the beneficiary's TrOOP balance and gross covered drug costs will also include the beneficiary's co-payment level, if the beneficiary is a dual eligible or LIS eligible. Although the TRR will provide the subsidy level of record to the new plan, consistent with CMS policy concerning "best available data" reflected in section IV. E. of this document, the transferring plan my have more up-to-date information than is currently reflected in CMS systems. This would not be a change for the regular EOB, but would involve only the transfer EOB. Because this proposed additional information would not be available from data reported on the regular EOB and would have to be retrieved from another source, CMS invites industry comment on whether the additional information would be sufficiently valuable to the new plan of record to warrant its inclusion.

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J. Special Transition Period for Retroactive Enrollment Situations

For 2007, CMS is proposing to implement a special transition period with important COB implications that would require Part D plans to provide limited reimbursement for covered Part D drugs for a time immediately preceding the minimum 30- or 90-day transition period. This requirement would be applied 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 except for those beneficiaries who had a special enrollment period and did not exercise it.

Although CMS is working with the States to identify as many individuals as possible in advance of the date they would 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 proposing to require 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 except for those beneficiaries who had a special enrollment period (SEP) and did not exercise it. The length of the SEP is determined by the specific circumstances under which the SEP was provided; e.g., the SEP for an institutionalized individual is the period of their institutionalization and up to 2 months after they move out of the facility.

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During the special transition period, normal transition rules would apply, but plans would be responsible for the allowable charges 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, would 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 would prefer that plans, to the extent they are able, do this electronically rather than by processing paper claims.

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K. Sharing Formulary Information with Other Payers

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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.

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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.

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L. Sharing Claims Data

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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.

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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, is currently finalizing the "Post Adjudication Standard" for approval. 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. We have attached a model Patient Drug History Data Sharing Agreement (Enclosure TBD) that has been developed for States and Medicare Part D Plans to use. These agreements must be in place prior to executing file transfers between States and Medicare Part D Plans.

M. 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). This document provides clarification regarding a limited number of MSP situations; however, all MSP laws shall be properly applied whether or not they are specifically mentioned here.

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. Therefore, it is 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 (WCMSAs), 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. The 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 www.cms.hhs.gov/WorkersCompAgencyServices

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

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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 (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 COBC. Should CMS change this process, however, Part D plans must notify us in the manner we specify.

N. 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.

P. Payment Reconciliation

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. 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. It

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is likely, therefore, that plans will continue to use the special prescription drug event submission and reimbursement processes established this year.

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.

Retroactive resolution 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 and 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).

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's or beneficiary's liability, the plan must re-adjudicate the claim within its own system

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without involving the pharmacy. This is most likely to occur when the plan corrects beneficiary cost-sharing levels.

Part D 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 that result from the collection of these claims and should not transfer this responsibility to pharmacies.

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.

Therefore to ensure effective coordination between Part D Plans and SPAPs and other entities providing prescription drug coverage, CMS has required Part D Plans to implement a 180-day timely claims filing limit for claims incurred January 1 through June 30, 2006. This affords pharmacies when not at fault for the original billing error adequate opportunity to reverse and rebill such claims. This claims filing window is necessary to accommodate the identification and resolution of coordination of benefits issues requiring claims reversal and rebilling to appropriate payers. We propose to continue to require a 180-day claims filing limit for plans until the NCPDP standard is able to automatically distinguish between pharmacy billing errors and payer and/or payer order errors. We are interested in receiving comment on whether this is an appropriate time limit for 2007.

V. Coordination of Benefit Activities of Non-Part D Payers

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A. Reporting the Existence of Prescription Drug Coverage Provided to Enrollees

As discussed in section II.A of this document, we expect that other payers will provide information regarding any other prescription drug coverage that their Medicare enrollees may have. As noted above, 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. Payers should report this information to CMS both when their coverage is primary to Medicare and when it is secondary to Medicare. Other payer information should be reported to the COBC through the various processes and agreements CMS makes available. Although we cannot require other payers to report the prescription drug coverage they provide their Medicare enrollees, we strongly encourage them to do so. Other payers will benefit from participating in the data sharing agreements described in section II.A because participation reduces mistaken payments and administrative costs when Medicare is primary (which happens most of the time). Participating in CMS's data exchange programs will also provide other payers with access to enrollment file sharing that may help them better structure their prescription drug coverage to supplement the benefits offered under Part D. In addition, by making their claim payments a matter of record with the Part D plans, other payers provide the means for Part D plans to execute reimbursement of erroneous payments, such as those that may occur in reimbursing excessive 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.

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 COBC 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/.

B. 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 unique RxBIN and/or PCN combination to each separate plan they offer in order to distinguish among all of their plans. 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 above (in section A). Payers primary to Medicare will continue to use their existing BIN and/or PCN. Not all other prescription drug coverage will have Rx identifiers. For instance, incident-related, non-group health plan, Medicare secondary payer insurance, such as Worker's Compensation, does not normally provide electronic, point-of-sale benefits; and SPAPs that offer premium assistance only will not have Rx identifiers. In

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other situations, the COBC may discover other prescription drug coverage, but be unable to identify the Rx identifier. The COBC will apply the information to MBD so that the plans are at least aware of the other coverage and can attempt to find more information about it.

C. Supplying Claims Information When a Supplemental Payment is Made

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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 may be accomplished automatically by tagging a claim response with the unique identifiers detailed in section V.B of this document in order for the claim to be captured in the TrOOP facilitation process (or by returning a claim response that was previously tagged by the pharmacy). However, if the other payer is aware that the TrOOP facilitation process failed, that it was not used for some other reason, or if the other payer does not have electronic claims capability, the payer may submit batch claims tagged with the unique identifiers to the TrOOP Facilitation Contractor, or submit batch or paper claims directly to the Part D plan in order for this information to be available for TrOOP calculations by Part D plans.

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D. Coordinating with Part D Plans for Payment of Premiums

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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 D.

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E. Following Medicare Secondary Payer (MSP) Laws and Order of Payment Standards

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As discussed in section II. C, in order to provide a consistent standard for the order of payment on Part D claims and 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 observe a consistent order of payment. MSP statutes and regulations apply to all payers providing prescription drug coverage. Other payers must become aware of and follow MSP rules. Clarification regarding a limited number of MSP situations is provided below; however, all MSP rules apply whether or not they are mentioned in this document.

1. Flexible Savings Accounts (FSA), Health Savings Accounts (HSAs), Archer Medicare Savings Accounts (MSA)

The MSP laws do not affect the status of FSAs, HSAs, and MSAs; these accounts are secondary to Medicare even when the MSP laws make their attached group health plans primary. However, Health Reimbursement Arrangements (HRAs) are treated as group health plans and are primary in the circumstances that trigger

the application of the MSP laws. Information about HRAs should be reported to CMS in the same manner as group health plan information is reported.

2. 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 II.A 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.)

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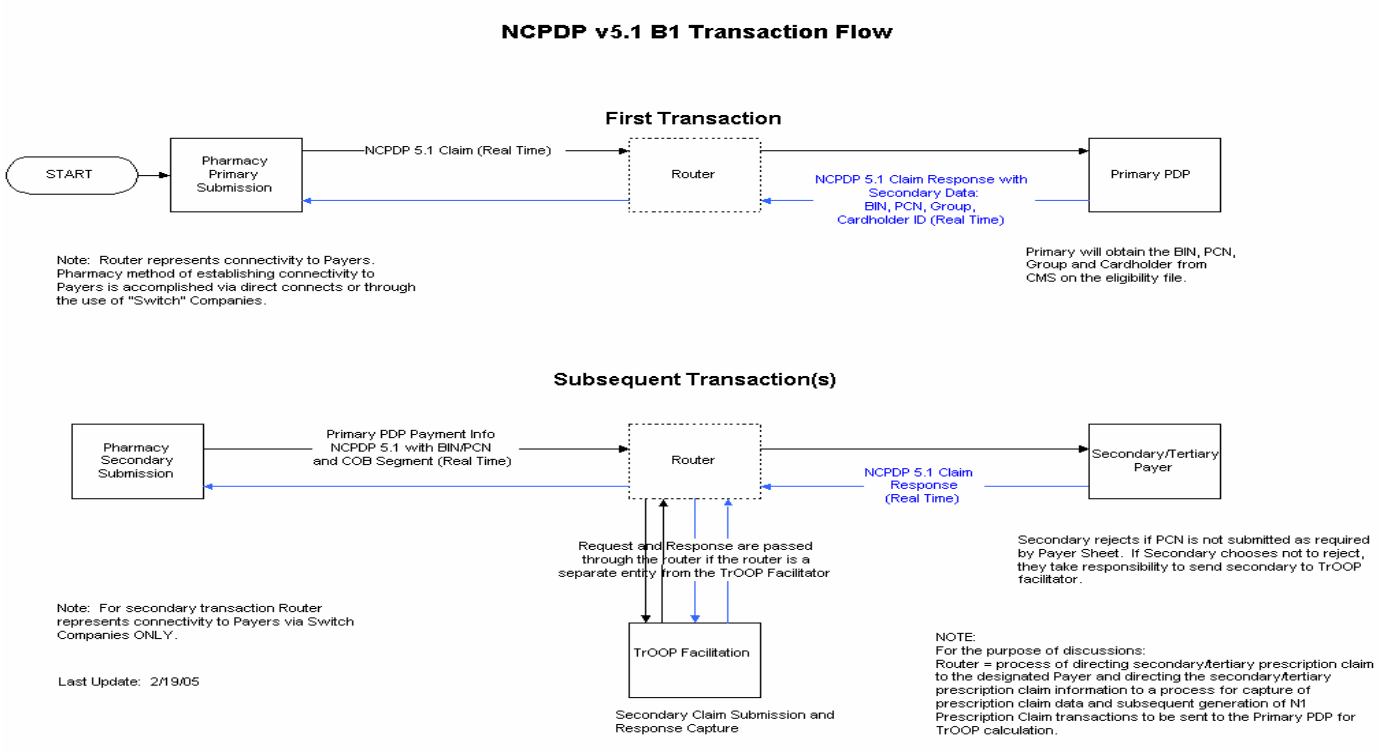
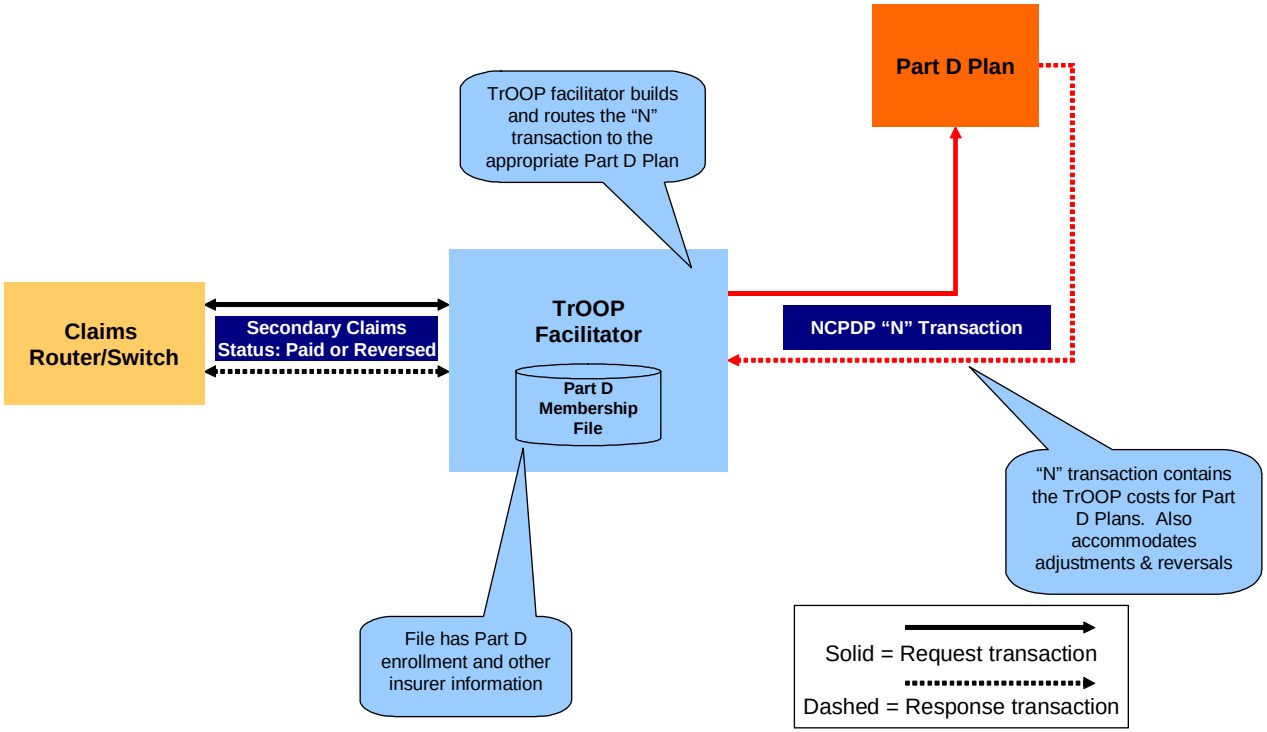
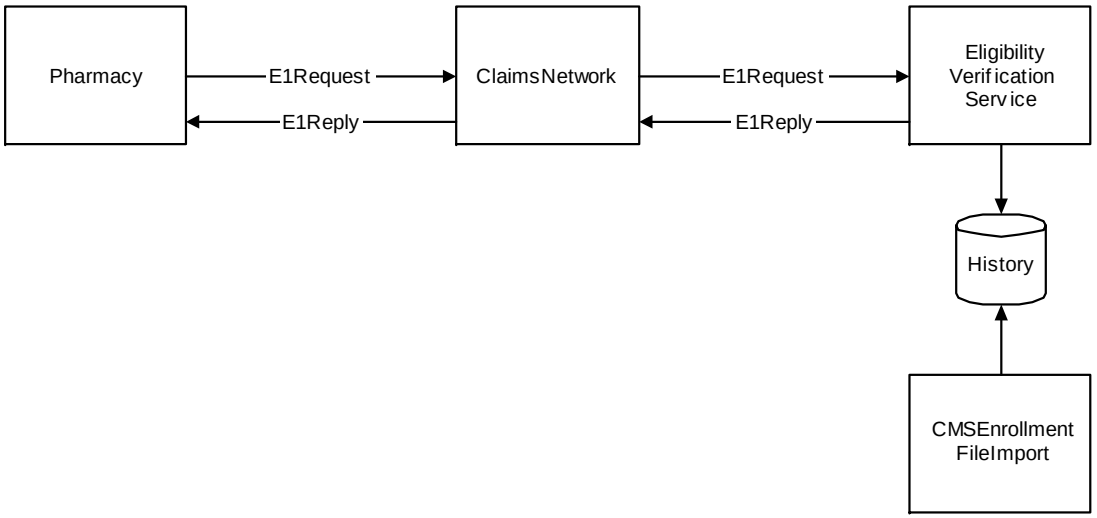
Appendix A: TrOOP Facilitation Process



TrOOP Facilitation



Eligibility Transaction



Appendix B: COB Survey

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Appendix C: Issues for Other Entities Providing Prescription Drug Coverage

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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)

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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 II.A. 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 intend to 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

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As mentioned in section L. "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 states and 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. More information regarding states and plans drug history exchanges are discussed in the section L.

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Coordinating Payment

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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

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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 IV. G. of this document, 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,

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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 IV. L, 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 plans, 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 that 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 with no cost-sharing to a beneficiary, but only if a beneficiary is

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Deleted: Currently under Medicare Parts A and B, individuals entitled both to Medicare and Veterans' benefits can get treatment under either program but must decide which benefits they are going to use because Medicare and the VA generally cannot pay for the same service. To receive services under VA benefits, a beneficiary must go to a VA facility or have the VA authorize services in a non-VA facility. To the extent that a beneficiary receives VA authorized services in a non-VA facility that doesn't cover all services rendered, Medicare can pay for the Medicare-covered part of the services that the VA doesn't pay. ¶
¶
Given the comprehensiveness of VA coverage, we anticipate that most Medicare beneficiaries with VA coverage will not enroll in Medicare Part D. However, to the extent that they do, information about VA coverage a Part D enrollee has 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.¶

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Deleted: Currently under Medicare Parts A and B, individuals entitled both to Medicare and TRICARE benefits must be enrolled in Medicare Parts A and B to receive TRICARE benefits. Generally, Medicare pays first for Medicare-covered services, and TRICARE pays the Medicare deductible and coinsurance for anything not covered by Medicare that TRICARE also covers. Medicare does not pay for services received from a military hospital or other federal provider.

enrolled in a Part D plan and the drug is covered by the Part D plan as the primary payer on the claim.

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 COBC and available to Part D plans as part of the COB process, through the MARx system. Any beneficiary payments do not count toward either gross covered drug costs or TrOOP under a Part D plan.

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 of 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 HIPPA-approved NCPDP standard for I/T/U pharmacies that are not

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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.

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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.

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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. Given the vulnerable population these programs serve, and considering that the low-income subsidies may not reach all needy beneficiaries (particularly those between 150 and 200 percent of the Federal poverty level who do not qualify for low-income subsidies

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under Part D), we believe that PAPs that assist low-income Medicare beneficiaries will be particularly important for beneficiaries when their cost-sharing under Part D is high – for example, in the deductible and coverage gap ranges of the benefit. However, PAPs that are sponsored or funded by pharmaceutical manufacturers should be carefully scrutinized for compliance with the fraud and abuse laws.

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.

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 accrued $3,600 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.

The option of operating outside the Part D benefit 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.

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 voluntary data sharing agreements, as described in our coordination of benefits guidance. 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

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Deleted: Although the OIG is the final arbiter of PAPs' compliance with Federal fraud and abuse laws, we believe there may be a number of problems associated with imputing a value to product donated by manufacturer PAPs for purposes of calculating TrOOP. Our final regulations specify that costs will be treated as "incurred" – meaning costs that count toward TrOOP – only if they are paid by the Part D enrollee or by another person on behalf of the individual. Given that our definition of the term "person" encompasses charities, incurred costs should be limited to those Part D drug costs actually paid by the PAP on behalf of the individual. Amounts above a PAP's actual costs would not count toward TrOOP because such amounts are not actually paid by the PAP on behalf of the beneficiary. Thus, the PAP could only apply the cost it incurs in making such a drug available – and not, as has been suggested, an average wholesale price (AWP) or average sales price (ASP) for the drug, or even a Part D plan's negotiated price for that drug – toward a beneficiary's TrOOP expenditure total. We interpret cost incurred by the PAP on behalf of the beneficiary as the direct cost of manufacturing the drug in addition to some reasonable administrative costs associated with its distribution. We do not believe it is appropriate to include, for example, costs associated with research and development or marketing and promotion. Because manufacturers may be reluctant to make public such costs given competitive concerns, this may be a less appealing option for structuring PAPs that serve Part D enrollees. ¶
¶
Based on several conversations with the industry, we understand that a useful model – and one that has worked well in practice – is to issue eligible PAP members a retail ID card that they can present at point of sale to obtain PAP financial assistance through a copay-assistance program. Beneficiaries enrolled in PAPs could therefore, through electronic coordination via our TrOOP facilitation process, have relevant PAP financial assistance applied at the point of sale, and that assistance would be automatically counted toward their TrOOP expenditures In other words, to the extent that PAPs want to be set up to pay benefits at the point-of-sale ar… [7]

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 or subsidized products through the PAP without affecting either TrOOP or total drug spend amounts on plan PDE records.

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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. However, if parties wish to consider these options, they should take appropriate steps to ensure that they comply with federal fraud and abuse laws. To that end, we recommend that PAPs wishing to pursue any alternative models consult existing Office of the Inspector General (OIG) guidance or request an advisory opinion through the OIG's advisory opinion process to ensure their programs are compliant with Federal fraud and abuse laws.

Personal Health Savings Vehicles

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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)

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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 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 wishes 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.

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Medicare Part B Coverage

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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 .

Field Code Changed

Part B coverage for home infusion therapy is generally limited to a number of drugs that require the use of an infusion pump in the home. Any agents administered in the home via IV drip or push injection would be covered under Part D. Although the Medicare Part D benefit does not cover equipment, supplies, and professional services associated with home infusion therapy, it does cover the ingredient costs and dispensing fees associated with infused covered Part D drugs. Some MA plans are seeking ways to keep people out of institutional settings and have proposed bundling home infusion drugs for payment purposes with home infusion services, equipment, and supplies in order to reduce hospitalizations and other costly health care settings. We agree that bundling could be especially appropriate for drugs treating acute conditions, as it may assist in more efficient enrollee transitions from hospital to home care settings, and will allow MA plans the option of covering home infusion drugs under Part C as a supplemental benefit, provided the plan consistently applies the option (i.e., the drug in question is always covered under Part C or always covered under Part D for the plan year). CMS will issue further operational guidance on bundling of home infusion drugs and ancillary services, equipment, and supplies for contract year 2007.

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In the preamble to our final regulations regarding the Part D program, we established an alternate process for payment of claims associated with the physician administration of Part D drugs and biologicals (primarily vaccines, but also other Part D drugs appropriately dispensed and administered by a physician). This was necessary given the lack of a ready mechanism for physicians who are out-of-network providers to bill Part D plans for the ingredient costs associated with these drugs and biologicals. This process requires that a Part D enrollee self-pay the physician for the vaccine costs and submit a paper claim for reimbursement to his or her Part D plan. The Part D plan is required to reimburse the beneficiary up to the plan allowable, minus any applicable cost-sharing, for that vaccine.

Since that time, Part D sponsors and drug manufacturers have expressed concern that this is not the most efficient process for routing Part D vaccine claims to Part D plans, particularly from the beneficiaries' and physicians' perspective. We have strongly encouraged Part D sponsors to develop additional approaches that minimize the need for out-of-network coverage involving up-front, out-of-pocket payment and the need for the beneficiary to submit paperwork to his or her plan for reimbursement. There exists a range of potential in-network and facilitated out-of-network approaches that avoid forcing the beneficiary to pay the full cost of the vaccine at the time of the visit. Examples of in-network approaches include delivery or administration by network pharmacies or specialty pharmacies where permitted. Examples of out-of-network approaches include paper-based vaccine notices or a web-based reimbursement program for physicians' offices. Plans are not limited to these approaches and are encouraged to pursue the implementation of any cost-effective, real-time billing option at the time of vaccine administration. Additionally, plans may consider adopting several approaches depending upon the vaccine and its respective cost, storage requirements, and complexity of administration.

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We established an alternate policy for claims processing associated with the physician administration of Part D drugs and biologicals (primarily vaccines, but also other Part D drugs appropriately dispensed and administered by a physician), given the lack of a ready mechanism for physicians to bill Part D plans for the ingredient costs associated with these drugs and biologicals. This policy requires that Part D enrollees self-pay the physician for the vaccine costs and submit a paper claim for reimbursement to his or her Part D plan. Costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals.¶
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Potential Part D sponsors and drug manufacturers have expressed concern that this is not the most efficient process for routing Part D vaccine claims to Part D plans, particularly from the beneficiaries' and physicians' perspective. In order to minimize burden, we strongly encourage Part D plans to work with industry and involve specialty pharmacies operating as network providers to facilitate these services. These pharmacies could accept vaccine claims from physician offices via the Internet, phone, or fax, and could divide the claim, sending the vaccine administration fee to the Part B carrier and the ingredient cost claim to the appropriate Part D plan. This process would not require the enrollee to self-pay for the drug at the time of the office visit or require the enrollee to submit a … [8]

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We expect that other payers will provide information regarding any other prescription drug coverage that their Medicare enrollees may have. Payers should report this information to CMS both when their coverage is primary to Medicare and when it is secondary to Medicare.

CMS coordinates benefits with other payers 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 through the use of Voluntary Data Sharing Agreements (VDSAs) Coordination of Benefits Agreements (COBAs) and other processes. For Part D, the COB Contractor will compare the list of other payers' enrollees to the current population of Medicare enrollees, will capture and maintain this other payer information, and will transmit the information to the Medicare Beneficiary Database (MBD) on a daily basis. For more information about current Medicare COB processes, please consult: http://www.cms.hhs.gov/medicare/cob/.

We are modifying all current COB data collection and exchange activities specifically to account for prescription drug coverage enrollment information. Generally, we expect that other payers will enter into agreements to periodically submit an input file of enrollees to the COB contractor. In return, the payer will receive a response file from the COB contractor indicating which of its enrollees are Medicare Part D beneficiaries. The payer will send input files and get response files back in standard formats. We will provide the final record layouts, business rules other payers can use to program their internal systems, official data sharing agreements, and other relevant information about this process via separate technical guidance as soon as they are available.

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When a Part D plan or a beneficiary provides information to the COB Contractor about other coverage, the COB Contractor will validate this information. This validated information will be captured and maintained in the CMS database and transmitted to both the TrOOP Facilitator and Part D plans.

The COB Contractor will provide plans with some assistance in determining a payer's TrOOP eligibility through this validation process. The contractor will crosswalk insurance type indicators to TrOOP eligibility. Further guidance on this will be forthcoming. However, Part D plans remain ultimately responsible for confirming the TrOOP-eligibility of other payer payments and applying these correctly to beneficiary TrOOP calculations. The COB Contractor will provide a help desk functionality that, among other things, will help plans tie a particular RxBIN/PCN combination to a particular payer so that plans can follow up with that payer and make a final determination in their systems regarding the payer's TrOOP status. We also note that the other payer information conveyed to Part D plans will include a payer help desk number.

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The COB Contractor will perform a daily update of information on other coverage to the CMS database. Plans must establish connectivity with our systems which, among other things, will allow Part D plans to have direct access to other payer status information as

often as their business requirements indicate. The COB Contractor will push out updated information to plans every business day. It will be 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 (via the ECRS system).

CMS will establish an electronic interface between Part D plans and the COB Contractor. The interface will allow Part D plans to submit post-enrollment transactions that change or add to currently-known COB information Part D plans will be updated on the status of these transactions as they move through the COB systems and will be informed on the determination made by the COB Contractor on the transactions via a COB data report/file. The data provided by the COB Contractor on supplemental payers and order of payment will be 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 COBC is unaware of some payers who have submitted batched claims after the point-of-sale transaction at a network pharmacy. Part D plans should also be aware that, in the case of retroactive eligibility for the low-income subsidy, Part D plans will be required to retroactively adjust claims and TrOOP balances based on prescription drug even (PDE) and claims records, as provided in 42 CFR 423.800(c). CMS will provide installation and user guides, as well as installation software, to Part D plans as soon as possible, but no later than September 1, 2005.

Plans will also 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.

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We believe that this approach allows for a simplified method for SPAPs (and other payers) 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
- Could work just as well for other payers, if desired.

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 be required to 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.

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Each Part D plan will be required to establish a process for the transfer of TrOOP balance information when a beneficiary disenrolls from its plan and reenrolls in another Part D plan mid-year. We note that CMS is considering the possibility of automating this crossover of TrOOP balances as part of the disenrollment/re-enrollment processes; however, this option will not be available in the beginning of the program in early 2006. In the meantime, plans should develop alternative processes to provide beneficiaries and other Part D plans with information on TrOOP and gross drug spend balances at the time of disenrollment, and periodically thereafter as required to provide updates on late claims. For example, plans may wish to consider providing that information to disenrolling members via an explanation of benefits (EOB), with instructions to the beneficiary to provide a copy of the EOB to the new Part D plan in which the beneficiary enrolls. Plans may need to send beneficiaries more than one EOB to reflect the retroactive adjustment of TrOOP balances given late claims.

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Sample business associate contract language is available on the Department of Health and Human Services' Office for Civil Rights (OCR) Privacy of Health Information website at: http://www.hhs.gov/ocr/hipaa/contractprov.html. In addition to business associate contract language, OCR's website contains helpful information to assist covered entities (including Part D plans) in complying with the HIPAA Privacy Rule.

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Although the OIG is the final arbiter of PAPs' compliance with Federal fraud and abuse laws, we believe there may be a number of problems associated with imputing a value to product donated by manufacturer PAPs for purposes of calculating TrOOP. Our final regulations specify that costs will be treated as "incurred" – meaning costs that count toward TrOOP – only if they are paid by the Part D enrollee or by another person on behalf of the individual. Given that our definition of the term "person" encompasses charities, incurred costs should be limited to those Part D drug costs actually paid by the PAP on behalf of the individual. Amounts above a PAP's actual costs would not count toward TrOOP because such amounts are not actually paid by the PAP on behalf of the beneficiary. Thus, the PAP could only apply the cost it incurs in making such a drug available – and not, as has been suggested, an average wholesale price (AWP) or average sales price (ASP) for the drug, or even a Part D plan's negotiated price for that drug – toward a beneficiary's TrOOP expenditure total. We interpret cost incurred by the PAP on behalf of the beneficiary as the direct cost of manufacturing the drug in addition to some reasonable administrative costs associated with its distribution. We do not believe it is appropriate to include, for example, costs associated with research and development or marketing and promotion. Because manufacturers may be reluctant to make public such costs given competitive concerns, this may be a less appealing option for structuring PAPs that serve Part D enrollees.

Based on several conversations with the industry, we understand that a useful model – and one that has worked well in practice – is to issue eligible PAP members a retail ID card that they can present at point of sale to obtain PAP financial assistance through a copay-assistance program. Beneficiaries enrolled in PAPs could therefore, through electronic coordination via our TrOOP facilitation process, have relevant PAP financial assistance applied at the point of sale, and that assistance would be automatically counted toward their TrOOP expenditures In other words, to the extent that PAPs 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 TrOOP Facilitation 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, PAPs 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.

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We established an alternate policy for claims processing associated with the physician administration of Part D drugs and biologicals (primarily vaccines, but also other Part D drugs appropriately dispensed and administered by a physician), given the lack of a ready mechanism for physicians to bill Part D plans for the ingredient costs associated with these drugs and biologicals. This policy requires that Part D enrollees self-pay the physician for the vaccine costs and submit a paper claim for reimbursement to his or her Part D plan. Costs directly related to vaccine administration may be included in physician fees under Part B, since Part B pays for the medically necessary administration of non-Part B covered drugs and biologicals.

Potential Part D sponsors and drug manufacturers have expressed concern that this is not the most efficient process for routing Part D vaccine claims to Part D plans, particularly from the beneficiaries' and physicians' perspective. In order to minimize burden, we strongly encourage Part D plans to work with industry and involve specialty pharmacies operating as network providers to facilitate these services. These pharmacies could

accept vaccine claims from physician offices via the Internet, phone, or fax, and could divide the claim, sending the vaccine administration fee to the Part B carrier and the ingredient cost claim to the appropriate Part D plan. This process would not require the enrollee to self-pay for the drug at the time of the office visit or require the enrollee to submit a paper claim for reimbursement to his or her Part D plan. The use of specialty pharmacies to process Part D claims in physician offices would automate the process and minimize burden for physicians and enrollees who are not required to self-pay—an especially important feature for dual eligible beneficiaries. While we strongly encourage plans to investigate and adopt this or other internal processes to facilitate the billing of vaccines, we do not establish a requirement to do so.