Part D Coordination of Benefits Guidance

I. Overview

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 will also serve an additional function within the Part D context: it will provide 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 2006, under the defined standard Part D benefit, catastrophic coverage is triggered only after $3,600 of TrOOP expenditures.

The MMA provided us with authority to impose user fees to defray the costs of Part D COB activities, as well as to retain a portion of those user fees to offset costs associated with the TrOOP facilitation process. The MMA prohibits our levying of user fees on SPAPs, however. In our regulations, we clarify that only Part D plans – not SPAPs or other payers – 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 will collect for COB. Thus, for example, Part D plans may not charge user fees for activities such as the costs of the claims transaction by supplemental payers (since Part D user fees funded

by CMS will be 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 will be issued in other communications.

II. CMS Requirements

CMS will leverage 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 will support the tracking and calculation of enrollees' TrOOP balances by Part D plans.

A. Enrollment File Sharing

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.

B. Validation of Information about Other Payers

When a Part D plan or a beneficiary provides information to the COB Contractor about other coverage, the COB Contractor 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.

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.

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, does not generally take place in pharmacy benefit management today. In the absence of significant change, this would mean that Part D plans would have to separately set up

procedures to coordinate benefits with every other payer with responsibility for drug coverage for one of their Part D enrollees.

However, in response to CMS's request for comment on the feasibility of an online real-time process, representatives from pharmacies, pharmacy benefit management (PBM) companies and pharmacy data processing and standard-setting organizations have provided extensive input and comments to design an automated solution for COB and the facilitation of the TrOOP accounting process. The industry has been working in collaboration with the National Council of Prescription Drug Programs (NCPDP) to develop a TrOOP facilitation concept of operations 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 will be required to utilize the existing industry standard NCPDP 5.1 transaction set to solve the problem of communicating 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 will detail the processing requirements involved in the TrOOP facilitation process.

On May 11, 2005, CMS awarded a contract to NDC Health to act as the TrOOP Facilitation Contractor for Part D claims processing. The TrOOP Facilitation Contractor, in conjunction with CMS, will be responsible for establishing procedures for facilitating eligibility queries at POS, identifying costs that are being reimbursed by other payers, and for alerting Part D plans about such transactions.

For instances in which Part D plan enrollees' secondary coverage is captured upfront by CMS systems as envisioned, multiple-payer claims will be automatically adjudicated at the POS. The TrOOP Facilitation Contractor will capture secondary payer claims transactions based on unique routing information collected previously at enrollment or through the COB Contractor's system. The TrOOP Facilitation Contractor will also have 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 could 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.

Part D plans will need to note information about a payer's TrOOP eligibility status based on the information it receives from our COB Contractor 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 will play an integral role in claims processing and TrOOP accounting, and CMS will engage pharmacists in extensive outreach efforts so that they fully understand how they will interact with these systems. For more detail about the TrOOP facilitation process, please see Appendix A. In addition, separate technical guidance on this process will be forthcoming shortly.

III. Beneficiary Requirements

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.

CMS expects that beneficiaries will 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.

IV. Part D Plan Requirements

A. Surveying Beneficiaries Regarding Other Prescription Drug Coverage and Transmitting Such Information to CMS

As provided in the MMA, beneficiaries are legally obligated to report information about other prescription drug coverage or reimbursement for prescription drug costs that they have or expect to receive; any material misrepresentation of such information by a beneficiary may constitute grounds for termination of coverage from a Part D plan. Part D plans must therefore regularly survey their enrollees regarding any other prescription drug coverage they may have and report that information – including, if known, any Rx identifiers (RxBIN, PCN, RxGRP, and RxID) – to the COB Contractor so that it can be validated, captured, and maintained in the CMS database for COB purposes. This survey should be performed within 30 days of enrollment and (at least once annually) thereafter, and should collect the same information on other payers that Part D plans must submit electronically to the COB Contractor. Part D plans will also be responsible for sending electronic updates about their enrollees' other sources of prescription drug coverage to the COB Contractor.

While we recognize that Part D plans may create efficiencies by collecting other payer information at the time of enrollment, our enrollment systems are not currently set up to accept complete other payer information. Furthermore, this method of collecting other payer information would not capture the information of auto-enrolled full benefit dual

eligibles, or other passively enrolled individuals (for instance, plan "rollovers"). We will consider whether our systems can be modified at a later time to accommodate other payer information with the submission of enrollment forms. However, until such time, we will require plans to survey their enrollees, as specified above.

B. Connectivity to CMS Systems

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 <u>all other</u> 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.

C. 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 will assist in this process by providing a TrOOP Facilitation Contractor (described in section II.D of this document) that will require that Part D plans use the existing industry standard NCPDP 5.1 transaction set to solve the problem of communicating other payer transactions back to

the primary Part D plan for purposes of tracking TrOOP in real time. In other words, Part D plans will be required to process claims and track TrOOP in real time by using this industry standard. CMS expects that Part D plans will establish policies and procedures appropriately restricting the use of paper claims to those situations in which on-line claims processing is not available to the beneficiary at the point of sale in order to promote accurate TrOOP accounting, as well as to minimize administrative costs to the Part D plans and the Medicare program and opportunities for fraudulent duplicative claim reimbursements

In cases in which secondary payer information is not captured upfront in CMS systems, however, Part D plans will be required to retroactively adjust claims and TrOOP balances using whatever methodology the plan determines to be most appropriate. CMS will also establish an order of payment (see section II. C) to the validated payer identifying data that will be pushed out through the electronic interface between Part D plans and CMS. This order of payment will assist 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 will be required to retroactively adjust claims and TrOOP balances when errors are made in terms of order of payment.

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 will be required to process claims in real time to support the TrOOP facilitation process. 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. However, plans should be aware that we will arrange technical calls through our TrOOP Facilitation Contractor and other groups to provide more guidance on this process, and that version C.1 of the NCPDP Implementation Guide will be 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 amounts as satisfying the deductible, regardless of whether or not the entire amounts count toward TrOOP.

As mentioned in section II.B, CMS will provide plans with some assistance in determining a payer's TrOOP eligibility. Once the Part D plan gets an updated eligibility file, it will become the Part D sponsor's responsibility to make this determination. 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.

D. Accepting Payment of Premiums from Other Payers

As provided by the MMA, supplemental payers may wish to pay premiums on behalf of Part D enrollees instead of (or in addition to) providing wrap-around coverage. While Part D plans must accept premium payments by supplemental payers on behalf of their Part D enrollees, the details of such arrangements will be 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.

In addition to accepting payment of premiums from other payers, Part D plans may wish to consider, for example, 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.

E. 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 vis-à-vis 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. It is important to note, however, that the cost sharing paid by means of the lump sum amounts will generally only apply toward TrOOP if made by a qualified SPAP or a charity for Part D benefits, and if made for expenditures on covered Part D drugs before a beneficiary reaches the annual out-of-pocket limit.

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

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

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

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

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.

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 (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.

F. 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.

G. Transferring TrOOP Balance When Beneficiary Changes Part D Plans

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.

H. Sharing Formulary Information with Other Payers

Although Part D plans may share detailed information about their formularies (in electronic format) with other payers upon request, there is no specific requirement that they do so. We are considering options via which other payers and providers would have centralized access to detailed formulary information, including a search tool for provider and other organizations that would for searches of Part D plans offering baskets of drugs on a state-by-state basis. 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.

I. Sharing Claims Data

We do not have the authority to require data exchanges between Part D plans and the States except as required for COB purposes. While the MMA requires Part D plans to allow SPAPs and other entities providing prescription drug coverage to "coordinate" with them, this language does not support requiring coordination of anything but payment. However, we strongly encourage Part D plans to independently share historical and ongoing data on these shared enrollees with other payers – particularly with States – provided such disclosure is consistent with the requirements of the 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.

J. 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, etc.). Clarification regarding a limited number of MSP situations is provided below; however, all MSP laws shall be properly applied whether or not they are mentioned in this document. Part D plans must make a good faith effort to learn of situations in which Part D drugs will be included as part of workers' compensation future medical payments. "Future medicals" are those services and items provided after the final settlement.

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 workers' compensation (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 WC settlements. One method of protecting Medicare's interest is Workers' Compensation Medicare Set-Asides (WCMSA's) which set aside certain settlement monies for future medical expenses. WCMSA's are applicable in settlements for all Medicare beneficiaries and also for individuals who are within 30 months of Medicare enrollment and possess a settlement greater than $250.000.

When the funds in a WCMSA are exhausted, Part D plans must notify CMS so that the MSP occurrence may be terminated. This is currently accomplished by reporting the exhaustion of the set-aside to the COB Contractor. Should CMS change this process, however, Part D plans must notify us in the manner we specify.

K. 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 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. 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.

V. Other (Supplemental) Payer Related Activities

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 COB Contractor 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 COBAs and VDSA (as described in section II. A) given that such coordination will help reduce mistaken payments and administrative costs, since in most cases, Part D will be primary to other coverage . 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 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.

We are modifying COB data collection and exchange activities specifically to account for prescription drug coverage enrollment information. The data exchange agreements require payers to periodically submit an input file containing certain enrollee populations. In return, the payer will receive a response file from the COB contractor indicating which of its enrollees are Medicare Part D beneficiaries. For more information about the COB process offered by CMS, please see: www.cms.hhs.gov/medicare/cob/.

B. Obtaining and Reporting Rx Identifiers

Payers supplemental to Medicare should obtain a unique RxBIN and/or PCN combination that will identify their paid claims responses for TrOOP tracking purposes in 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.

C. Supplying Claims Information When a Supplemental Payment is Made

In order for the COB and TrOOP tracking processes to function as effectively as possible, other payers should supply paid claims information to the Part D plan after making a payment that is supplemental to a Medicare payment. This may be accomplished 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.

D. Coordinating with Part D Plans for Payment of Premiums

If another payer 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.

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

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)

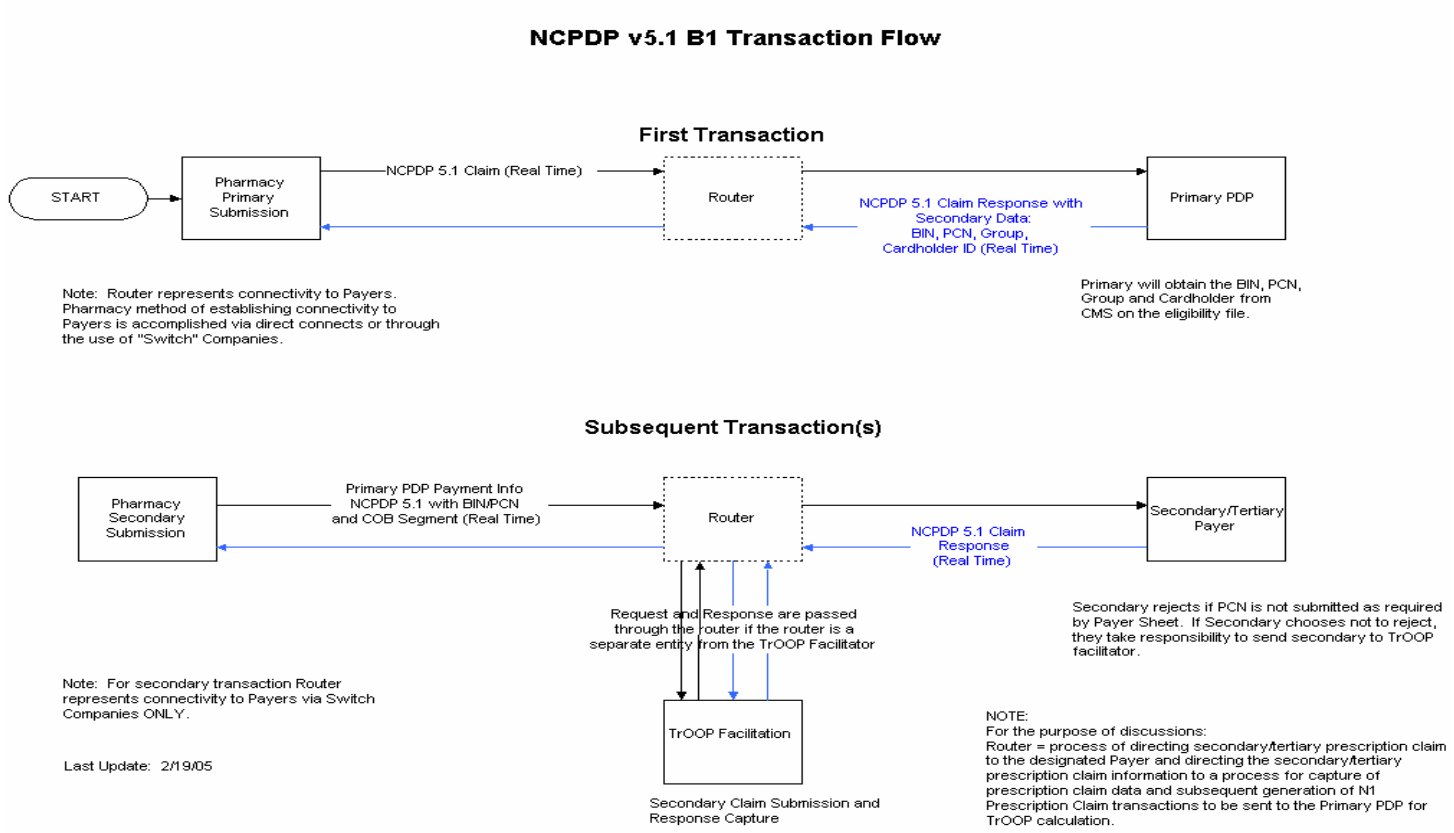
For MSP purposes, FSAs, HSAs, and MSAs are not group health plans and thus are not subject to being a primary payer under MSP laws. Health Reimbursement Arrangements (HRAs) are group health plans, however, and MSP laws apply to these accounts accordingly. Information about HRAs should be reported to CMS in the same manner as group health plan information is reported.

2. IRS/SSA/CMS Data Match

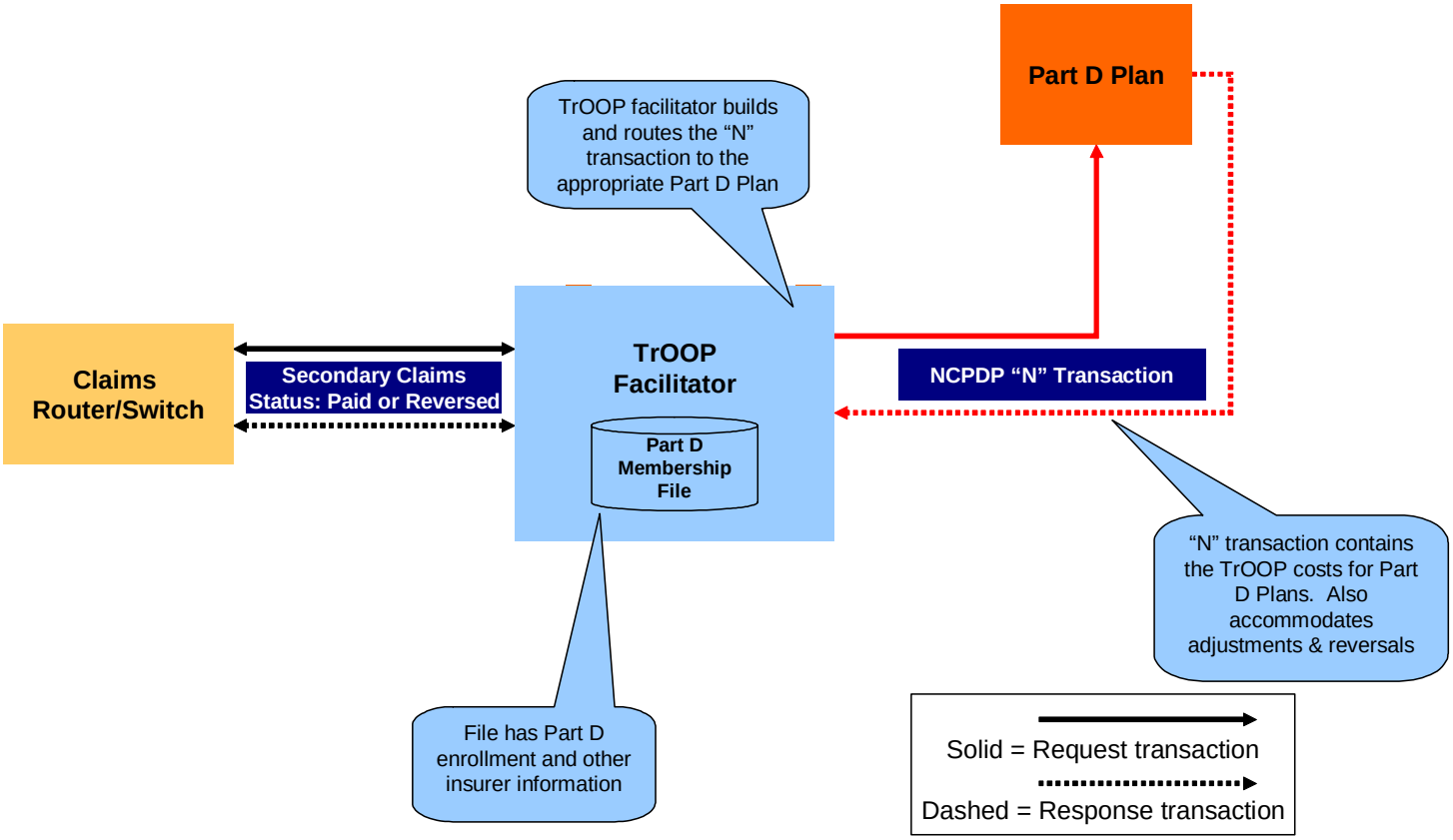
IRS/SSA/CMS Data Match requirements pursuant to the Consolidated Omnibus Budget Resolution Act of 1989 (COBRA ‘89) apply to prescription drug coverage. Employers required to complete Data Match forms must include prescription drug information – including their ordinary RxBINs, PCNs, RxGRPs, and RxIDs – on their Data Match forms. Data Match requirements may be

fulfilled by obtaining a voluntary data sharing agreement (VDSA), as described in section II.A of this document, 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.)

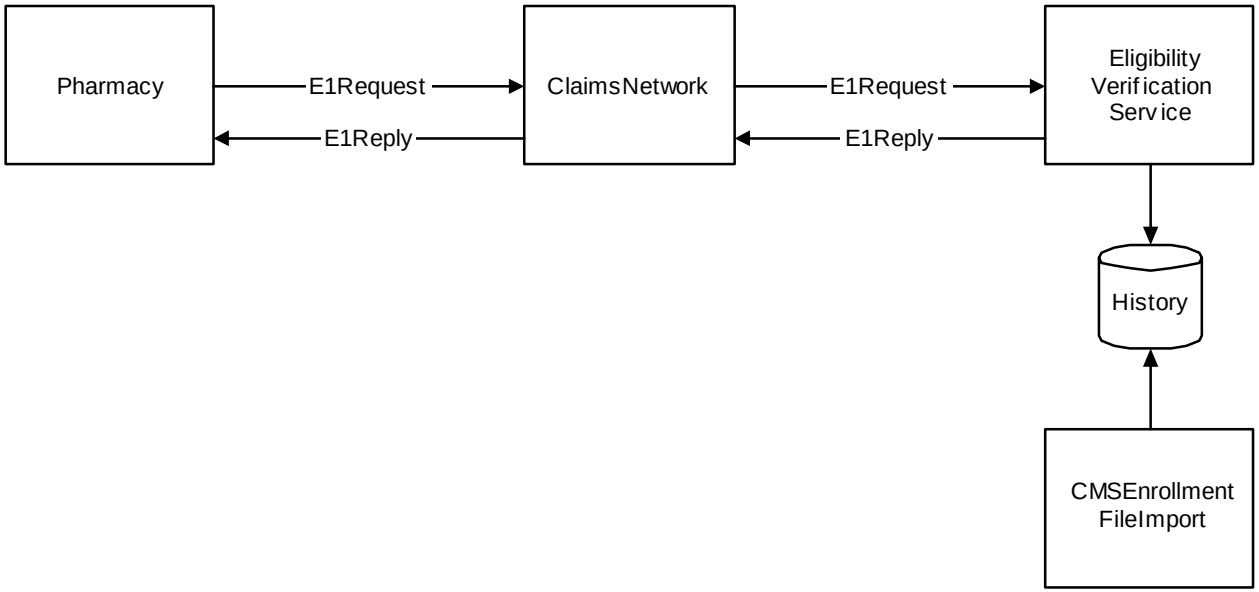
Appendix A: TrOOP Facilitation Process



TrOOP Facilitation



Eligibility Transaction



Appendix B: Issues for Other Entities Providing Prescription Drug Coverage

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

State Pharmaceutical Assistance Programs (SPAPs)

Qualified SPAPs are unique among other payers because any payments supplementing the benefits available under Part D coverage before a beneficiary reaches the annual out-of-pocket limit made on their enrollees' behalf count toward TrOOP. We expect that qualified SPAPs will share enrollment files with CMS through the data sharing arrangements outlined in section 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.

As mentioned in section IV.I 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 Part D 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. We believe claims data exchanges will be mutually beneficial to States and Part D plans as they structure their benefits.

Certain SPAPs may have the authority to enroll their members directly into Part D plans if using an enrollment methodology (random assignment or intelligent random assignment) 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.

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

Medicaid

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

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. However, there is no automated process at this point for this notification via our TrOOP facilitation protocol given that Medicaid is not an alternate payer of Part D claims.

As discussed previously, 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.

VA Coverage

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.

TRICARE

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.

Given the comprehensiveness of TRICARE coverage, we anticipate that most Medicare beneficiaries with TRICARE coverage will not enroll in Medicare Part D. However, to the extent that they do, information about TRICARE coverage a Part D enrollee 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.

Indian Health Service (IHS)/Tribal Health Coverage

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). We do not believe there is currently any capability under the NCPDP 5.1 transaction set for I/T/U pharmacies 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 a linkage 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. We note that in certain areas, Tribal organizations using tribal-only money may qualify as TrOOP-eligible payers, so Part D plans may have to set up (manual) processes to receive this information and to adjust calculations accordingly.

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 are important examples of key components of the safety net.

Many of these providers offer access to prescription drugs and pharmacy services to their own patients and not to the public at large. This access may be provided through a "closed pharmacy" – one that is not open to the general public. These pharmacies are typically smaller and less visible to the public than more commonly identified retail pharmacies. An estimated 12,000 safety net providers participate in HRSA's 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.

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. To the extent these facilities provide any wrap-around coverage to Part D benefits after payment of the claim by the Part D plan, claims from these pharmacies (whether electronic or paper, to the extent some of the more remote safety net pharmacies lack electronic capability) or other processes established between the pharmacy and the Part D plan should include complete information about those subsidies so that they are not applied to the beneficiary's TrOOP balance by the Part D plan.

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 340B 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 for that purpose, will not count toward that beneficiary's TrOOP expenditures.

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.

In our final regulations implementing the Medicare Part D benefit, we clarified that regardless of whether a manufacturer 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 manufacturer PAP makes on behalf of Part D enrollees will count toward TrOOP for those enrollees.

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 <u>on behalf of</u> 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.

Personal Health Savings Vehicles

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

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

AIDS Drug Assistance Programs (ADAP)

AIDS Drug Assistance Programs (ADAPs), which are funded under the Ryan White CARE Act, are an integral component of the safety-net for HIV/AIDS patients because they fill coverage gaps in public and private insurance for critical HIV/AIDS drug treatments. Although assistance with Part D cost-sharing 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 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, ADAPs may require beneficiaries to submit paper claims after the POS transaction and can then submit those claims to the TrOOP Facilitation Contractor in batch form. The TrOOP Facilitation Contractor will create an NCPDP N1 transaction based on that batched claims data and will send it back to the beneficiary's Part D plan for accurate TrOOP recalculation.

Medicare Part B Coverage

We considered, but did not establish, automatic cross-over procedures for situations in which a Part B carrier denies a claim under Part B and then submits the claim to the appropriate Part D plan (or its claims processing agent) via the TrOOP Facilitation Contractor. As stated in the preamble of our final rule, we were concerned that these procedures could not be developed by January 1, 2006 given the many other systems and implementation challenges to be addressed before then. While CMS will continue to investigate automatic claims processing procedures, we believe this will probably require changes in HIPPA reporting standards to accommodate the complete information exchange needed for both Part B Carriers using the established ASC X12N 837 format for claims processing and Part D plans who must adopt NCPDP 5.1 industry standards for drug claim processing. Since changes to the HIPAA standards may take several years to be approved, this is not likely to be a short-term solution.

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.