DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: May 21, 2010

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director, Medicare Drug Benefit and C & D Data Group
Cheri Rice, Deputy Director, Medicare Plan Payment Group

SUBJECT: Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance

This memorandum provides Part D sponsors with the revised Medicare Coverage Gap Discount Program guidance and the Centers for Medicare & Medicaid Services' (CMS) responses to summary public comments received in response to the draft guidance released on April 30, 2010. CMS appreciates the efforts of everyone that submitted comments in response to the draft guidance. Many of these comments persuaded CMS to make changes to this guidance and other comments that are not addressed in this Part D sponsor guidance will be considered for future guidance. This guidance supersedes the draft guidance that was issued on April 30, 2010.

Responses to Summary Public Comments on the Draft Medicare Coverage Gap Discount Program Guidance:

Comment: Several commenters requested that CMS provide the revised model explanation of benefits (EOB) as soon as possible in order to allow sufficient time for Part D sponsors to implement the changes.

Response: CMS expects to release the revised model EOB in June.

Comment: Many commenters requested that CMS publish and maintain an updated list of all NDCs covered under manufacturer discount agreements in addition to the list of labeler codes that CMS will be providing. These commenters believe this is necessary to ensure consistent application of the discount across the Part D program.

Response: CMS does not have access to better information than Part D sponsors, and since the beginning of the program, we have delegated the responsibility for making Part D drug coverage

determinations to Part D sponsors. Similarly, we believe Part D sponsors must determine which drugs are applicable drugs for purposes of applying a discount. However, CMS will work with the FDA to make information on NDCs more transparent and readily available to the public so that Part D sponsors can accurately determine which products represent applicable drugs subject to the discount, and will do our best to make it clear to the public which labeler codes are covered by agreements and which labeler codes are not.

Comment: Several commenters requested that CMS specify additional notice requirements and develop model letters and notices to better inform beneficiaries about the discount program, negative changes in drug availability due to the discount program, and notices explaining how the discount is applied at point-of-sale.

Response: CMS appreciates the concern for ensuring that beneficiary educational materials and notices sufficiently address the implementation of the Discount Program and will take these suggestions under immediate consideration. We will provide future guidance to address any new requirements.

Comment: Several commenters requested that CMS clarify how it will determine exceptions for allowing coverage of applicable drugs not covered under manufacturer discount agreements when it is essential for the health of beneficiaries.

Response: CMS fully expects all manufacturers of applicable drugs to sign an agreement. CMS will carefully monitor manufacturer participation to ensure beneficiary access to drugs that are essential to the health of Part D enrollees.

Comment: Many commenters indicated that they interpreted the statute to apply the Discount Program to all Part D plan enrollees not eligible for a low income subsidy, regardless of whether the Part D plan in which they were enrolled was an employer group waiver plan (EGWP). They noted that, while the discounts do not apply where drugs are covered by supplemental benefits, employers do not necessarily provide supplemental benefits that partially cover or eliminate the coverage gap. One commenter, in contrast, argued that EGWPs should be excluded from the Discount Program because such plans fall within the definition of "qualified retiree prescription drug plan," and the statute makes clear that individuals enrolled in such plans are not eligible for the Discount Program. In the draft guidance, CMS requested specific comments on how the Discount Program should be applied to EGWPs given that CMS is unsure of the level of benefits provided in the gap.

Response: CMS has determined that EGWPs are included in the Discount Program because the definition of "applicable beneficiary" in §1860D-14A(g)(1) of the Social Security Act covers all Part D plan enrollees not eligible for a low income subsidy. The argument that EGWPs should be excluded from the Discount Program under the exclusion from the program of individuals in a "qualified retiree prescription drug plan" is refuted by the fact that the Affordable Care Act defines the term "qualified retiree prescription drug plan" as having the meaning given such term

in section 1860D-22(a)(2) of the Social Security Act, which clearly speaks only to those retiree plans that are not Part D plans.1

In the draft guidance, CMS raised questions about determining the level of discount that would be applied to EGWP claims given that we do not know what level of Part D supplemental benefits, if any, are applied to EGWP claims. CMS will address this in 2011 by allowing EGWPs to participate in the Discount Program if they can attest and/or otherwise demonstrate that their beneficiaries have cost-sharing between the plan initial coverage limit (ICL) and the catastrophic threshold and that they will apply any supplemental benefits before determining the applicable discount that will be reported on the PDEs. CMS reserves the right to audit EGWPs to further validate the information reported on PDEs. Beginning in 2012, CMS also will require EGWPs to submit additional benefit information detailing supplemental benefits to support the discount provided at point-of-sale and reported on the PDEs.

Comment: Almost all commenters recommended that CMS allow retroactive changes to applicable discounts, when necessary, when retroactive adjustments are made to claims or beneficiary eligibility. Some commenters recommend that retroactive changes to the applicable discounts should only apply when it is favorable to the beneficiary. Pharmacies commented that adjustments should not involve reversals of pharmacy claims that had been properly paid.

Response: CMS is persuaded that retroactive changes must apply to applicable discounts when retroactive changes are made to the claim or beneficiary eligibility. CMS was originally concerned that allowing retroactive changes would complicate the application of the discount but the comments have convinced us that such adjustments can be accurately applied to the discount. CMS incorporated changes in the final guidance to require retroactive adjustments to applicable discounts when necessary to reflect the retroactive changes to the claim or beneficiary eligibility. Consistent with our previous guidance, Part D sponsors should generally limit retroactive adjustments to pharmacies to claims in which pharmacy reimbursement changes as opposed to the distribution of sponsor, manufacturer and beneficiary liabilities.

Comment: Many commenters recommended that CMS allow Part D sponsors to apply the discount to all in-network paper claims for applicable drugs in addition to out-of-network claims, paid by the Part D sponsor.

Response: CMS has clarified that all "paper" claims submitted for reimbursement by beneficiaries for applicable drugs determined to be payable by Part D sponsors should be subject to the discount and we revised the final guidance to reflect this policy. Our draft guidance was never intended to differentiate paper claims for applicable drugs subject to discount from those that do not involve a discount. Rather, we were merely pointing out that the discount would only

1 Section 1860D-22(a)(2)(B) speaks of maintaining records "necessary to ensure the. . .accuracy of [RDS] payments made under this section" – payments which may not be made on behalf of a Part D plan enrollee under section 1860D-22(a)(4) -- and refers to the provisions of section 1860D-2(d)(3) applying "in a manner *similar to* [emphasis added] the manner in which they apply to . . . PDP sponsors and MA organizations" – further making clear that qualified retiree prescription drug plans do not include Part D plans.

be available on those paper claims submitted by beneficiaries (from either in-network or out-of-network) that should appropriately be paid under Part D.

Comment: Several commenters requested that vaccine administration costs and sales tax be excluded from the definition of negotiated price for purposes of determining the applicable discount.

Response: With the exception of the dispensing fee, the Affordable Care Act requires CMS to use the negotiated price defined in 42 CFR 423.100 for purposes of determining the applicable discount. This definition addresses the amount that a network dispensing provider will receive, in total, for a particular drug, and thus is not limited to the ingredient cost component of the negotiated price. CMS has consistently included sales tax and vaccine administration cost in the negotiated price reported on PDE records.

Comment: Several commenters requested that CMS clarify if multiple source products that are approved under NDAs but used by the Part D sponsors as a generic for purposes of cost-sharing in the initial coverage phase and catastrophic phase are subject to the discounts. Similarly, several commenters asked if "authorized generics" are subject to the discount.

Response: Neither section 3301 Affordable Care Act nor CMS' final guidance make any distinction between multiple source drugs or "authorized generic" drugs approved under new drug applications (NDA) versus any other applicable drug**.** We believe the definition of applicable drug includes all drugs approved under NDAs and, therefore, all such drugs are subject to the discount if covered under a manufacturer discount agreement. We removed the reference to "authorized generic" from the definition of "applicable drug" because it is our understanding that while most "authorized generics" are approved under NDAs others may be approved under abbreviated new drug applications (ANDAs). Only those "authorized generics" licensed by sponsors of NDAs are applicable drugs subject to the discount.

Comment: Several commenters requested that CMS allow transition coverage for drugs that potentially become excluded from Part D for failure of a manufacturer to sign a discount agreement.

Response: Transition coverage is only available for drugs that can be covered under the Part D program. The Affordable Care Act makes it clear that applicable drugs that are not covered under a manufacturer discount agreement cannot be covered under Part D, unless authorized by CMS under 1860D-43(c), and therefore, Part D sponsors may not provide transition coverage for such applicable drugs. However, CMS expects that all manufacturers of applicable drugs will sign discount agreements so there will be no changes in availability of covered Part D drugs.

Comment: One commenter recommended that CMS work with the TrOOP facilitator to establish a process for manufacturers to pay the manufacturer discounts at the point of sale. The commenter asserted that such an approach would reduce the risk of processing errors and reduce administrative costs for Part D sponsors and manufacturers.

Response: Based on our research, CMS does not believe that such an approach can be implemented at this time due to the existing HIPAA billing standards and other limitations in the transmission of information needed to determine the manufacturer discount amounts at the point of sale.

Comment: One commenter requested information regarding whether CMS will use the information provided in worksheet 6 of the Part D bid to determine the prospective discount program payments for Part D sponsors.

Response: At this time, CMS does not expect to use the estimates in worksheet 6 of the Part D bids to determine these payments. Instead, CMS will use the drug cost projections in worksheet 3 of the Part D bids (as applicable) to calculate the plan specific prospective discount program payments.

Comment: Many commenters requested clarification on the relationship between discounts that will be available under the Medicare Coverage Gap Discount Program and existing Part D rebate contracts. Specifically, these commenters asked if the manufacturer discounts were intended to replace the rebates that are currently made available to Part D sponsors.

Response: CMS believes that Congress' intent when enacting the Medicare Coverage Gap Discount Program was for the discounts not to replace rebates currently available to Part D sponsors. We expect that manufacturers will continue to negotiate with Part D sponsors and other entities to provide rebates on Part D drugs purchased throughout the Part D benefit and specifically in the coverage gap. CMS reminds Part D sponsors that they will have the opportunity to make some formulary changes during the August update window if necessary to address contracting changes that could otherwise affect their formularies.

Comment: Some commenters requested that CMS clarify whether the rebates and other price concessions received from manufacturers for Part D drugs are considered duplicate payments for the manufacturer discounts. In addition, the commenters asked whether Part D sponsors may receive rebates and other price concessions from manufacturers for the Part D brand drugs purchased in the coverage gap.

Response: The provisions in 30.2 are intended to ensure that Part D sponsors do not receive duplicate manufacturer discount payments under the Discount Program. These provisions do not prohibit Part D sponsors from receiving rebates or other price concessions from manufacturers. We expect that manufacturers will continue to negotiate with Part D sponsors and other entities to provide rebates on Part D drugs purchased throughout the Part D benefit and specifically `in the coverage gap, and we note that we believe Congressional intent of the program is for manufacturer discounts not to replace rebates currently available to Part D sponsors.

Comment: Two commenters requested guidance regarding whether the prospective discount payments received by Part D sponsors will be subject to retroactive adjustment for LIS status changes and other changes.

Response: Similar to other Part D prospective payments, the monthly prospective discount program payments made by CMS will be subject to retroactive adjustments due to changes in LIS status and other changes.

Comment: One commenter requested clarification regarding how sponsors should report administrative costs for the Discount Program in the 2011 bids. The commenter also asked for clarification regarding whether the administrative costs for the Discount Program projected in the Part D bids will be included in the determination of the administrative cost ratio used in the calculation of Part D risk sharing payments.

Response: Part D sponsors must include the administrative costs for the Discount Program in the administrative expense components of their Part D bids. These costs should be reported in the bid in the same manner as other administrative costs for the Part D program. Part D sponsors are not required to report these administrative costs separately for purposes of Part D payment reconciliation. Therefore, these costs will be included in the determination of the administrative cost ratio.

Comment: A few commenters requested additional information regarding the reconciliation process and the timing of the reductions to Part D sponsors' prospective payments to reflect discount amounts invoiced to manufacturers. One commenter requested that CMS provide sufficient time for plan sponsors to receive and process manufacturer discount payments prior to reducing Part D sponsors' prospective payments by these amounts.

Response: Additional information regarding the reconciliation process for discount program payments and the timing of the reductions to prospective Part D payments will be provided in later guidance.

Comment: Two commenters recommended that CMS provide member, plan ID, and prescription-level detail on the reconciliation reports provided to Part D sponsors.

Response: CMS will consider this comment as we develop the reconciliation reports for the Part D discount program. Additional guidance regarding the Discount Program reconciliation process will be provided at a later date.

Comment: One commenter stated that the Discount Program will increase the drug costs projected in the Part D bids because it will reduce the incentives for Part D beneficiaries to transition from brand drugs to generic drugs while in the coverage gap. The commenter also asserted that the Discount Program will increase Part D sponsors' administrative costs due to the administration of this complicated program and the lag time in the payments from pharmaceutical manufacturers.

Response: Even with the discounts for brand-name drugs upon implementation of the program, CMS believes that beneficiaries will continue to have strong incentives to use lower-cost drugs, including generics. CMS will carefully monitor changes in the use of brand-name drugs by Part D enrollees.

Comment: One commenter requested clarification regarding which parties will pay for the additional administrative costs incurred by Part D sponsors and the costs associated with the CMS contractor.

Response: Part D sponsors will include their estimates for additional administrative costs under the Discount Program in their Part D bids, which will be used to determine their beneficiary premiums and direct subsidy payments from CMS. The CMS contractor will coordinate the Discount Program as a component of the Part D program administered by CMS.

Comment: One commenter requested that CMS give manufacturers access to the discount program estimates provided by Part D sponsors in the Part D bids to assist with financial planning.

Response: Drug cost estimates provided by Part D sponsors in the Part D bids are considered proprietary. Furthermore, we do not believe that this information would aid manufacturers in estimating the discounts for their specific brand drugs. We note that Part D sponsors will not provide separate discount program estimates in the 2011 Part D bids.

Comment: A few commenters recommended that CMS establish deadlines for the submission of PDE records reporting manufacturer discount amounts to ensure that the coverage gap discounts are reported and invoiced on a timely basis. One commenter requested information regarding whether manufacturers will be invoiced for PDE records received after the close of the calendar year.

Response: Part D sponsors must submit their PDE records for the Discount Program within the current PDE submission deadlines for the Part D program. On average, Part D sponsors are expected to submit their PDE records within thirty days of claim receipt. For the Part D payment reconciliation, Part D sponsors must submit their PDE records within five months after the end of the contract year. CMS will continue to accept PDE records from Part D sponsors after the Part D payment reconciliation and invoice manufacturers for the discount amounts reported on these PDE records. We note that the PDE records submitted after the Part D payment reconciliation will not be subject to the Discount Program reconciliation described in section 30.3.

Comment: Several commenters recommended that the CMS Contractor provide detailed claim-level data to manufacturers to facilitate efforts by manufacturers to validate the invoiced discount amounts. Commenters requested additional information regarding the data provided on manufacturer invoices and the timing of the quarterly manufacturer invoices.

Response: CMS appreciates the comments received regarding the data that will be provided on manufacturer invoices. CMS will provide additional information regarding the data that will be provided on manufacturer invoices in subsequent guidance.

Comment: Several commenters requested that CMS provide to Part D sponsors a copy of the invoices sent to manufacturers. Receiving a copy of the invoices would ensure that Part D sponsors are aware of the amounts invoiced to manufacturers.

Response: We agree. A copy of the detail on invoices sent to manufacturers, specifically the portion that is related to the sponsor in question, will be provided to Part D sponsors.

Comment: Several commenters indicated that manufacturers will need more than 15 days to review, validate, and pay the invoiced discount amounts. Commenters recommended that CMS consider a longer payment period similar to the payment period for Medicaid. Specifically, commenters requested a payment period of 45 days or 60 days. One commenter recommended that CMS establish timeframes for manufacturer payments that are consistent with the current Part D prompt payment provisions at §423.520 of the Part D regulations. Another commenter supported the 15 day payment period proposed by CMS.

Response: Manufacturers will be required to pay the invoiced manufacturer discounts to Part D sponsors within the payment period established in the Model Manufacturer Discount Program Agreement. The comments received will be considered when developing the final Model Manufacturer Discount Program Agreement.

Comment: Several commenters indicated that requiring manufacturers to pay the invoiced manufacturer discount amounts to Part D sponsors directly would be administratively burdensome for manufacturers and Part D sponsors. Commenters recommended that CMS require manufacturers to pay the invoiced discount amounts to the CMS contractor or CMS for distribution to Part D sponsors. Commenters indicated that this approach would provide one point of contact for manufacturers and Part D sponsors and improve the efficiency of the Discount Program. One commenter recommended CMS collect the manufacturer discount payments from manufacturers and reimburse Part D sponsors during the next monthly payment cycle. Some commenters have suggested that requiring manufacturers to pay the manufacturer discounts to Part D sponsors instead of CMS or a CMS contractor is inconsistent with the Discount Program provisions in the statute.

Response: We disagree. The Discount Program provisions in the statute do not permit CMS to collect the discount payments from manufacturers. Per Section 1860D-14A(d)(2)(A), "the Secretary shall not receive or distribute any funds of a manufacturer under the program" unless (for 2011 only), such an action is required for implementation of the Discount Program. The statute also does not require that a third party administrator collect the discount payments from manufacturers. Section 1860D-14A(d)(3)(B) of the statute requires CMS to contract with a third party to "receive, distribute, **or** facilitate the distribution of funds of manufacturers to appropriate individuals or entities". While the CMS contractor will not receive the discount payments from

manufacturers, the CMS contractor will facilitate the distribution of these payments by developing and distributing the manufacturer invoices, ensuring that manufacturers have the information necessary to send their payments to the appropriate Part D sponsors, collecting information from manufacturers to verify timely and accurate payments to plan sponsors, and coordinating with Part D sponsors to ensure that payments were received in a timely manner. We do not believe that requiring manufacturers to pay the invoiced discount amounts directly to Part D sponsors would be overly burdensome. In addition, we believe that this approach is most consistent with the intent of the statute.

Comment: Several commenters requested that CMS remove the requirement that manufacturers pay disputed invoiced amounts. Commenters indicated that it would be inappropriate for manufacturers to pay amounts that they believe are incorrect. In addition, they indicated that such a provision would be inconsistent with the payment requirements under TriCare and the Medicaid program. One commenter indicated that this provision could create issues under the anti-kickback statute. Commenters requested additional information regarding the process for disputing the amounts on manufacturer invoices.

Response: We disagree with the commenters' recommendation. This requirement is necessary to ensure that the manufacturer discounts are paid to Part D sponsors in a timely manner and are not delayed due to disputed discount amounts. Additional information regarding the dispute resolution process will be provided in the draft Model Manufacturer Discount Program Agreement released for comment in the Federal Register on May 21, 2010. In cases where invoiced discount amounts are found to be inappropriate during the dispute resolution process, the revised payments will be reflected on future manufacturer invoices as a negative adjustment reducing the manufacturers total discount payments.

Comment: One commenter recommended that CMS establish a threshold for payments to Part D sponsors. The commenter asserted that establishing a threshold would reduce the administrative burden associated with manufacturers issuing checks for small payment amounts.

Response: The Affordable Care Act requires manufacturers to provide the funding for all manufacturer discounts made available to Part D beneficiaries under the Discount Program. Therefore, we believe that it would be inappropriate for manufacturers to withhold payment from Part D sponsors because the aggregate discount amount is low. In addition, we do not believe that making small payment to Part D sponsors will impose significantly greater burden on manufacturers.

The Medicare Coverage Gap Discount Program: Part D Sponsor Guidance

This guidance provides instructions to Part D sponsors for implementing the Medicare Coverage Gap Discount Program (the Discount Program), recently enacted into law in section 3301 of the Patient Protection and Affordable Care Act (H.R. 3590), as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (H.R. 4872)(HCERA)(together known as the Affordable Care Act) and codified in sections 1860D-43 and 1860D-14A of the Social Security Act (the Act). Section §1860D-14A(d)(5) authorizes CMS to implement the Medicare Coverage Gap Discount Program (Discount Program) through program instruction and this guidance serves as the program instruction to Part D sponsors. In accordance with §1860D-14A(d)(6), Paperwork Reduction Act requirements under 44 USC chapter 35 shall not apply to the Discount Program.

10 Introduction

In accordance with §1860D-14A(d)(5) of the Act, this guidance specifies the requirements and procedures for implementing the Discount Program. The guidance is divided into the following major sections:

- Section 20 -- Overview
- Section 30 -- Point-of-sale discounts
- Section 40 -- Manufacturer discount payments
- Section 50 -- Conditions for coverage under Part D
- Section 60 -- Applicable drugs
- Section 70 -- Applicable discounts for applicable beneficiaries
- Section 80 -- Dispute Resolution
- Section 90 -- Program Monitoring and Oversight
- Section 100 -- Definitions

20 Overview

The Medicare Prescription Drug Benefit was enacted into law on December 8, 2003, in Section 101 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) and is codified in Sections 1860D-1 through 1860D-42 of the Act. Section 101 of the MMA amended Titles XVIII of the Act by re-designating Part D as Part E and inserting new Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D"). The Part D program is available for individuals who are entitled to Medicare Part A or enrolled in Medicare Part B. The Centers for Medicare & Medicaid Services (CMS) contracts

with private companies, referred to as Part D sponsors, to administer the Part D program via stand alone prescriptions drug plans (PDPs) and prescription drug plans offered by Medicare Advantage Organizations (MA-PDs). The Part D program became effective January 1, 2006.

Standard Part D prescription drug coverage consists of coverage subject to an annual deductible, twenty-five percent coinsurance (or an actuarially equivalent cost-sharing design) up to the initial coverage limit (ICL), and catastrophic coverage for individuals that exceed the annual maximum true out-of-pocket (TrOOP) threshold with cost-sharing equal to the greater of a $2/$5 copayment or coinsurance of 5 percent. Under the standard coverage, individuals that do not receive additional cost-sharing subsidies from CMS or additional coverage by other secondary payers (e.g. State Pharmaceutical Assistance Programs) are responsible for paying one-hundred percent of the Part D negotiated price for covered Part D claims above the ICL until their TrOOP costs exceed the annual threshold amount. (The standard drug coverage will change beginning in 2011 for generic drugs and 2013 for applicable drugs as required by section 1860D-2(b), as amended by the HCERA.)

The Affordable Care Act, as amended by the HCERA, establishes the Discount Program by adding sections 1860D-43 and 1860D-14A of the Act. Effective January 1, 2011, the Discount Program will make manufacturer discounts available to applicable Medicare beneficiaries receiving applicable drugs while in the coverage gap. In general, the discount on each applicable drug is fifty percent of an amount equal to the negotiated price (as defined section 100.11 of this guidance). Unless CMS has authorized coverage under section 50.2 of this guidance, applicable drugs may be covered under Part D only if the manufacturer has a signed agreement with CMS to provide the discount on coverage gap claims for all of its applicable drugs and remains compliant with the terms of that agreement.

Beginning in 2011, Part D sponsors must provide the discounts for applicable drugs in the coverage gap at point-of-sale (POS). CMS will coordinate the collection of discount payments from manufacturers and payment to Part D sponsors that provided the discount to applicable beneficiaries through a contractor. This coordination will involve a standard process for paying Part D sponsors based on new information submitted to CMS on prescription drug event (PDE) data (see section 30.5).

30 Point-of-sale discounts

Section 1860D-14A(c)(1)(A)(ii) requires the discounts to be provided at POS. Discounts can be provided at POS only if the entity adjudicating the electronic pharmacy claim has the information necessary to determine at that point in time:

- the drug is a discountable drug;
- the beneficiary is eligible for the discount;
- the claim is wholly or partially in the coverage gap; and
- the amount of the discount, taking into consideration plan supplemental benefits that pay first.

CMS has determined that the only entity capable of providing the discount at POS is the Part D sponsor because no other entity will have all four pieces of information. Only the Part D sponsor knows which Part D drugs are on its formulary and which enrollees have obtained an exception to receive a non-formulary Part D drug. The Part D sponsor has the low-income subsidy (LIS) information for beneficiaries which is necessary to exclude such claims from discount consideration. The Part D sponsor tracks gross covered drug spend (GCDS) and TrOOP costs, which are necessary for determining when the beneficiary enters the coverage gap and exits the coverage gap, respectively. Moreover, only the Part D sponsor knows which portion of the claim is in the coverage gap. For example, if a beneficiary fills a $100 prescription when he or she is $50 below the initial coverage limit, only $50 of the claim will be subject to the discount. For these reasons, only the Part D sponsor can provide the discount at POS.

CMS thoroughly explored the viability of a model whereby a third party administrator (TPA) could directly adjudicate the discount payment to pharmacies. In this hypothetical model, the pharmacy would submit the Part D claim to the Part D sponsor and receive information on the response that would direct the pharmacy to bill the TPA for applicable claims. While this model initially showed promise, our research revealed that neither the current Health Insurance Portability and Accountability Act (HIPAA) electronic pharmacy claims billing standard nor the next HIPAA approved version of the billing standard could support the transfer of information from the Part D sponsor that would be necessary to specify the appropriate claims and appropriate discount amounts to be billed to a TPA, or allow for accurate coordination of benefits among payers. Consequently, CMS has determined that this model cannot be used to implement the Discount Program in the foreseeable future.

Therefore, starting on January 1, 2011, Part D sponsors must calculate the discount amount at the time of the initial claim adjudication and provide the discount amount in the adjudicated response and payment to the pharmacy. Sponsors must develop and implement processes to separately account for these amounts in order to populate PDEs and EOBs, as well as track receivables for reimbursement. CMS will incorporate changes into Part D contracts for purposes of implementing the requirement for Part D sponsors to provide the discount at POS.

30.1 Part D sponsors provide discount at point-of-sale

Part D sponsors shall provide the applicable discount on applicable drugs to applicable beneficiaries at point-of-sale, and shall reimburse the pharmacy for the applicable discount within the applicable number of calendar days (as defined in section 100.4 of this guidance), which is consistent with current Part D prompt payment requirements under 42 CFR 423.520.

30.2 Payments to Part D sponsors for Discount Program

CMS will provide monthly prospective payments to Part D sponsors for the manufacturer discounts made available to their enrollees under the Discount Program. These prospective discount program payments will be calculated based on the projections in each Part D plan's bid and their current enrollment. CMS will estimate the per member per month cost of the manufacturer discounts for each plan based on the coverage gap drug costs projected in worksheet 3 of their approved 2011 Part D bids. Specifically, CMS will subtract the projected

drug costs for generic drugs provided to applicable beneficiaries in the coverage gap from the total projected drug costs in the coverage gap and multiply the difference by 50%. Additional adjustments may be made to account for dispensing fees and each plan's LIS enrollment. This plan specific estimate will be made available to Part D sponsors in HPMS on the Part C & D Bid and Premium Information page. EGWPs do not submit Part D bids. Therefore, CMS will not have the information necessary to estimate the cost of manufacturer discounts for these Part D plans. Therefore, similar to our current policy for prospective low-income cost sharing subsidy and reinsurance subsidy payments, CMS will not provide prospective discount program payments to EGWPs. However, EGWPs will receive final reconciled discount program payments under the reconciliation process described in section 30.3.

Each month, CMS will determine the prospective discount program payment by multiplying the plan specific manufacturer discount estimate by the number of beneficiaries enrolled in the plan who are not eligible for the low-income subsidy. Part D sponsors will receive the prospective discount program payments on the first of each month with their other Part D prospective payments. The discount program payments will be reflected as a separate line item on each Part D sponsor's Monthly Membership Detail Reports and included in the Part D payments displayed on the Monthly Membership Summary Reports.

In order to ensure that Part D sponsors do not receive duplicate Discount Program payments for the manufacturer discounts made available to their enrollees, the prospective payments made to Part D sponsors will be reduced by the discount amounts invoiced to manufacturers under Section 40 of this guidance. This guidance makes no changes to negotiations between Part D sponsors or other entities with drug manufacturers to obtain additional rebates, discounts, or other price concessions for drugs purchased in the coverage gap or throughout the Part D benefit. CMS expects that manufacturers will continue to engage in such negotiations and provide such price concessions on drugs available throughout the benefit and in the coverage gap.

30.3 Reconciliation of Discount Program Payments to Part D Sponsors

After the end of the contract year, CMS will reconcile the prospective discount program payments that the Part D sponsor received from CMS to cost based on the actual manufacturer discount amounts made available to each Part D plan's enrollees under the Discount Program. The actual manufacturer discount amounts will be determined based on the manufacturer discount amounts reported by Part D sponsors on the prescription drug event (PDE) records. Part D sponsors will receive a report indicating their aggregate prospective discount program payments, the aggregate manufacturer discount amounts reported on their PDE records, and their reconciled manufacturer discount payments. As part of the Part D payment reconciliation process, these final reconciled discount program payments will be subject to the reopening and appeals provisions in 42 CFR 423.346 and 42 CFR 423.350. See section 30.5 of this guidance for information on the reporting of manufacturer discount amounts on the PDE records. This reconciliation process will ensure that Part D sponsors are fully reimbursed for the manufacturer discount amounts made available to their enrollees as reported on accepted PDE records.

Manufacturer discount amounts reported on PDE records submitted after the PDE submission deadline for the Part D payment reconciliation will not be subject to the reconciliation process described above. As described in section 40.1, these manufacturer discount amounts will be

invoiced to manufacturers and paid directly to Part D sponsors. However, CMS will not reduce Part D sponsors' prospective payments by the manufacturer discount amounts reported on the PDE records submitted after the PDE submission deadline for Part D payment reconciliation.

30.4 Part D Bidding Considerations

The prospective discount program payments will be calculated based on the information currently provided by Part D sponsors in their Part D bids. Therefore, Part D sponsors will not be required to provide a separate estimate for these manufacturer discount amounts in the Part D Bid Pricing Tool. With the exception of potential changes in drug utilization, the Discount Program does not affect how drug costs are reported and projected in the Part D bids. Part D sponsors, however, must include the administrative costs associated with administering the Discount Program in the administrative expense component of their Part D bids. The manufacturer discount amounts received under this Discount Program are not considered direct and indirect remuneration (DIR) because they do not serve to decrease the drug costs incurred by the Part D sponsor. Therefore, Part D sponsors must not include these manufacturer discounts in the rebate amounts reported in the Bid Pricing Tool.

30.5 Prescription Drug Event (PDE) Requirements

Part D sponsors will be required to report the manufacturer discounts made available to their enrollees under the Discount Program on the PDE records in a new field, "Reported Gap Discount." The amounts reported in the "Reported Gap Discount" field will be used for the cost-based reconciliation of the prospective discount program payments made to each Part D sponsor. CMS will conduct a series of edits in the Drug Data Processing System (DDPS) to ensure that the manufacturer discounts amounts reported on the PDE records were accurately calculated and applied by Part D sponsors. To facilitate validation of the amounts reported in the "Reported Gap Discount" field, CMS is adding several new fields to the PDE records including:

- Total Gross Covered Drug Cost Accumulator,
- True Out-of Pocket Balance Accumulator,
- Beginning Benefit Phase,
- Ending Benefit Phase,
- Brand/Generic Code,
- Tier, and
- Formulary Code.

Additional guidance will be provided about the new PDE fields for contract year 2011.

30.6 Explanation of Benefits

CMS is changing the model Part D EOB to highlight the applicable discounts that are provided by manufacturers on coverage gap claims. The 2011 model EOB will provide detail on the amount of the monthly prescription drug costs funded by the manufacturers through the Discount

Program to provide transparency to the beneficiary. Sponsors must be prepared to report separately on these amounts in the 2011 EOB. CMS expects to release a revised model EOB in June 2010.

40 Manufacturer discount payments

A CMS contractor will coordinate the collection of discount payments from manufacturers and payment to Part D sponsors that provided the discount to applicable beneficiaries. This coordination will involve a standard process for invoicing the manufacturers, providing instructions for reimbursing Part D sponsors, facilitating dispute resolution with manufacturers, and collecting information to ensure that invoiced manufacturer discount amounts are fully paid by manufacturers within the payment deadlines established in the manufacturer discount program agreements.

40.1 CMS contractor invoices Manufacturers for applicable discounts on behalf of Part D sponsors

A CMS contractor will conduct analysis to verify the accuracy of the manufacturer discounts reported by Part D sponsors in the "Reported Gap Discount" field of the PDE records. The CMS contractor will invoice each manufacturer quarterly on the behalf of Part D sponsors. Each manufacturer will be invoiced for the manufacturer discount amounts reported on the PDE records submitted to CMS during the applicable quarter, including PDE records submitted and accepted after the Part D payment reconciliation deadline. The invoices will be itemized at the 11 digit NDC level as determined by CMS and provide certain claim-level detail. A copy of the pertinent portions of manufacturer invoices will be provided to Part D sponsors as well.

Manufacturers will be required to pay the invoiced amounts to Part D sponsors directly using payment routing information collected by CMS for each Part D sponsor and distributed to the Manufacturer. Manufacturers must pay the entire invoiced amount including any amounts in dispute within the payment periods established in the manufacturer's discount program agreement with CMS. In the draft model manufacturer discount program agreement released for comment in the Federal Register on May 21, 2010, CMS proposes that manufacturers pay invoiced amounts to Part D sponsors within 14 days of receipt. Additional information regarding manufacturer invoices and the dispute resolution process for the Discount program will be provided in the draft model manufacturer discount program agreement.

50 Conditions for Coverage under Part D

Beginning January 1, 2011, §1860D-43(a) of the Affordable Care Act limits Part D coverage for applicable drugs to only those applicable drugs of manufacturers that have:

- Agreed to participate in the Discount Program;
- Entered into and have in effect an agreement with CMS to pay the discounts under the Discount Program; and

- Entered into and have in effect a contract with CMS' contractor.

50.1 General Rule--All Applicable Drugs Must be Covered under a Manufacturer Agreement.

Unless CMS has authorized coverage under section 50.2 of this guidance, all applicable drugs must be covered under a manufacturer discount agreement with CMS for coverage to be available under Part D. CMS will implement this requirement by having the manufacturer specify in the discount agreement the labeler code(s) that are covered under the agreement. The labeler code is the first five digits of a drug product's 11 digit national drug code (NDC) and identifies the company that assigned the NDC to the drug product. A manufacturer must specify all of its labeler codes in an agreement so that all of the manufacturer's applicable drugs will be covered under the agreement.

CMS will maintain an updated list of the labeler codes that are covered by the manufacturer discount agreements, distribute the list to Part D sponsors and post the list on the CMS website. CMS expects to make the 2011 list public by October 1, 2010 and update it annually after the January 30th deadline for manufacturers to enter into agreements or terminate agreements for the following plan year.

Part D sponsors must provide prospective notice to affected Part D enrollees (as defined in 42 CFR 423.100) if a covered Part D drug will no longer be covered for failure of a manufacturer to sign a manufacturer discount agreement. In addition, because applicable drugs that are not covered under a manufacturer agreement cannot be covered under Part D, Part D sponsors will not be able to cover any such products under exceptions, emergency first fill, or transition policies, unless CMS has authorized coverage under section 50.2 of this guidance.

50.2 Exception--Authorizing Coverage for Drugs not Covered under a Manufacturer Discount Agreement

Section 1860D-43(c) provides CMS with the authority to allow coverage of applicable drugs that are not covered by manufacturer discount agreements if CMS determines that:

- The availability of the drug is essential to the health of Part D enrollees; or
- There are extenuating circumstances for 2011.

CMS expects that all manufacturers of applicable drugs will sign discount agreements so there will be no changes in availability of covered Part D drugs. However, CMS will notify Part D sponsors if any applicable drug not covered by a manufacturer agreement has been determined to be essential for the health of Part D enrollees and exempt from the manufacturer agreement requirement.

Extenuating Circumstances for 2011

CMS does not intend to apply the "extenuating circumstances" authority authorized for 2011 as we fully expect all manufacturers of applicable drugs to sign the agreement so that there will be no changes in the availability of coverage for Part D drugs.

60 Applicable drugs

Manufacturers only will provide a discount for "applicable drugs" with respect to "applicable beneficiaries." An applicable drug, as defined in §1860D-14A(g)(2) of the Act and section 100.2 of this guidance is a covered Part D drug (as defined in section 100.5 of this guidance) that is either approved under a new drug application (NDA) under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (BLA).

Applicable drugs covered by a Part D sponsor under transition and emergency fill policies, as well as under exceptions and appeals processes are subject to applicable discounts for applicable beneficiaries.

Drugs excluded from Part D under section 1860D-2(e)(2)(A) are not applicable drugs subject to an applicable discount even if covered by the Part D sponsor under an enhanced benefit.

In order for Part D sponsors to provide the discount on applicable drugs only, the Part D sponsor must identify those NDCs for covered Part D drugs that are approved under NDAs or licensed under BLAs. CMS will continue to work with the FDA to make this information more transparent and readily available to Part D sponsors to assist with making these determinations.

70 Applicable discounts for applicable beneficiaries

In accordance with §1860D-14A(g)(1) of the Act, section 100.1 of this guidance defines an "applicable beneficiary" as an individual who, on the date of dispensing a covered Part D drug, is:

- Enrolled in a prescription drug plan or an MA-PD plan;
- Not enrolled in a qualified retiree prescription drug plan;
- Not entitled to an income-related subsidy under section 1860D-14(a); and
- Who has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) during the year; and has not incurred costs for covered Part D drug in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B).

Enrollees in Employer group health and waiver plans (EGHPs & EGWPs) are eligible for participation in the Discount Program if they otherwise satisfy the definition of applicable beneficiary in section 100.1 of this guidance.

Part D sponsors will need to identify these applicable beneficiaries and apply the appropriate discount at point-of-sale, taking into consideration the following additional program guidance:

70.1 Supplemental Coverage

Section 1860D-14A(c)(2) specifies that if a Part D sponsor offers supplemental Part D coverage, the discount will not be applied until after such supplemental coverage has been applied to the applicable drug. If the supplemental coverage completely eliminates the coverage gap so that a beneficiary has no cost–sharing at all, no discount is available because the discount is only applied to the portion of the negotiated price that falls within a coverage gap. Therefore, PACE plans that have no coverage gap by statutory design are excluded from the Discount Program.

For 2011, any Part D plan that wishes to offer Part D supplemental benefits on applicable drugs covered between the plan's initial coverage limit (ICL) and the Medicare Part D catastrophic threshold using coinsurance will use the rules described as follows: Plan, manufacturer and beneficiary liabilities shall be determined at the claim level. The value of supplemental benefits that must be calculated first on any claim for an applicable drug will consist of the difference between the proposed supplemental coinsurance and coinsurance under the basic benefit (100% for 2011). Thus, for a brand drug supplemental benefit of 60% coinsurance, the value of the supplemental benefits that must be applied first (plan liability) would be 40% (100% - 60%) of the negotiated price of the drug. We interpret the dispensing fee for any such claim to be included in the plan liability portion of the claim. The amount of the discount would then be calculated as 50% of [the negotiated price (as defined in 42 CFR 423.100) less the supplemental benefit]. Beneficiary cost sharing will be the remainder of the negotiated price after the plan liability and discount amounts have been applied.

CMS continues to confirm how supplemental benefits using fixed copays would work with the Discount Program and will issue additional instructions along with PDE guidance.

CMS will consider additional benefits provided by EGWPs to be Part D supplemental benefits and allow EGWPs to opt in to the Discount Program if they demonstrate that that their benefit includes any cost-sharing between the ICL and the catastrophic threshold. CMS will require EGWPs to provide additional information to us regarding their 2011 benefits and will specify these requirements in future guidance.

Finally, if Medicare Part D is not the primary payer, no applicable discount is available because the beneficiary would not have a coverage gap on the initial claim to the primary payer.

70.2 Application of Discount before other health coverage

In accordance with §1860D-14A(c)(1)(A)(v), Part D sponsors shall apply the applicable discount before any coverage or financial assistance under other health benefit plans or programs (e.g. State Pharmaceutical Assistance Programs (SPAPs), Aids Drug Assistance Programs (ADAPs), Indian Health Service) that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries. Since the Part D sponsor will

"pay" for the discount at the same time as its primary payment on the claim, this coordination will take place in real time as the claim is adjudicated by the pharmacy.

70.3 *"*Straddle" Claims

If an applicable beneficiary has a claim for an applicable drug that "straddles" the coverage gap and another phase of the Part D benefit, §1860D-14A(g)(4)(C) requires that Part D sponsors only provide the discount on the portion of the negotiated price of the applicable drug that falls at or above the ICL and below the annual out-of-pocket threshold. Because negotiated price, as defined in section 1860D-14A(g)(6), excludes the dispensing fee, we interpret the dispensing fee for any straddle claim to be included in the portion of the negotiated price that falls below the ICL or above the annual out-of-pocket threshold. This policy supports the statutory goal of alleviating the burden of the coverage gap on applicable beneficiaries.

70.4 Date of dispensing/Retroactive adjustments

Part D sponsors shall use the "date of dispensing," as defined in section 100.7 of this guidance, for purposes of providing a discount at POS and determining the amount of such discount, if any. However, if later information retroactively changes effective eligibility for the applicable discount back to the date of dispensing (e.g. retroactive low-income subsidy status changes, or retroactive changes resulting from automated TrOOP balance transfers via Financial Information Reporting (FIR) transactions), Part D sponsors shall make retroactive adjustments to the applicable discount as necessary to reflect the retroactive changes to the claim or beneficiary eligibility. For example, if a claim for an applicable drug was originally adjudicated in the initial coverage phase but is later moved into the coverage gap as a result of receipt of an automated TrOOP balance transfer from a previous Part D sponsor, the applicable discount should be applied to the adjusted claim. Conversely, if an original claim was adjudicated in the coverage gap with an applicable discount but later reprocessed in the catastrophic phase as a result of an automated TrOOP balance transfer, the applicable discount should be refunded to the manufacturer.

Retroactive adjustments that affect the applicable discount generally should be handled in the same manner as all other retroactive adjustments. Consistent with our previous guidance, Part D sponsors should generally limit retroactive adjustments to pharmacies to claims in which pharmacy reimbursement changes as opposed to changes in the distribution of sponsor, manufacturer and beneficiary liabilities. If such adjustments are made as the result of a coverage determination process, the Part D sponsor shall comply with coverage determination timelines for purposes of making determinations and issuing any refunds due to the beneficiary.

70.5 Point-of-sale Exceptions

Part D sponsors shall provide the applicable discount for applicable drugs submitted by applicable beneficiaries via paper claims, including out-of-network and in-network paper claims submitted by Part D enrollees, if the Part D sponsor determines that such claims are otherwise payable under Part D.

70.6 Part D compounds

Part D sponsors shall only provide a discount on a compound if the NDC submitted on the PDE (for the most expensive Part D drug ingredient) is for an applicable drug. The Part D sponsor shall only provide the discount on the negotiated price (as defined in section 100.11 of this guidance) of the applicable drug submitted on the PDE because only that NDC is reported to CMS and only that manufacturer can be invoiced. The applicable discount for the NDC submitted on the PDE is the total discount that shall be provided for the compound.

80 Beneficiary Dispute Resolution

Part D sponsors must handle beneficiary inquiries and complaints about the Discount Program. CMS will provide scripting, but since Part D sponsors are responsible for advancing the discount, they must resolve all beneficiary questions and concerns. Part D sponsors should ensure that PDEs are submitted to CMS as soon as they are final in order to have the benefit of DDPS edit checks.

The discount payment is a Part D benefit and, therefore, beneficiaries shall have access to the existing Part D coverage determination and appeals process for disputes involving the availability and amount of manufacturer discount applicable to the Part D claims.

90 Program Monitoring and Oversight

Our centralized implementation plan, in which CMS or its contractor directly receives information necessary to determine compliance on the part of plan sponsors and manufacturers, results in a very transparent compliance picture.

Program Oversight
With respect to Part D sponsor compliance, CMS will implement a process to monitor the appropriate provision of discounts by Part D sponsors by periodically analyzing the PDE data. CMS intends to establish a new field(s) for PDE reporting that requires the Part D sponsor to specify that a discount was provided on the claim and the amount of that discount. In addition, CMS will rely on its complaint tracking protocol to monitor beneficiary complaints related to the Discount Program. CMS can verify drug, beneficiary and claim eligibility on a retrospective basis.

Monitoring the Program impact on Part D

CMS will also establish metrics to monitor the effect of the Discount Program on the overall Part D program. These metrics will monitor potential impact on areas such as:

- Part D drug prices
- Number of beneficiaries reaching catastrophic coverage
- Generic utilization rates

- Benefit designs
- Amount of rebates and other price concessions reported in DIR

CMS may determine that additional reporting requirements are necessary to oversee the operation and/or impact of the discount program, and may issue additional guidance in these areas.

100 Definitions

100.1 "Applicable Beneficiary" means an individual who, on the date of dispensing a covered Part D drug:

1. Is enrolled in a prescription drug plan or an MA-PD plan;
2. Is not enrolled in a qualified retiree prescription drug plan;
3. Is not entitled to an income-related subsidy under 1860D-14(a);
4. Has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) during the year; and
5. Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B). This does not mean that a beneficiary who has moved through the coverage gap is not eligible for cost while in the coverage gap.

100.2 "Applicable Drug**"** means, with respect to an applicable beneficiary, a Part D drug that is:

1. Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) or, in the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

2. i. If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;

ii. If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or

iii. Is treated as if on formulary, for instance when provided through an exception or appeal.

100.3 "Applicable Discount" means fifty percent of the portion of the negotiated price (as defined in 100.11) of the applicable drug of a Manufacturer that falls within the coverage gap (as defined in 100.6).

100.4 "Applicable Number of Calendar Days**"** means with respect to:

1. Clean claims (as defined in 42 CFR 423.520) for reimbursement submitted electronically, 14 days; and
2. Clean claims (as defined in 42 CFR 423.520) for reimbursement submitted otherwise, 30 days.

100.5 "Covered Part D drug" has the meaning as set forth in 42 CFR 423.100.

100.6 "Coverage Gap" means the gap phase in prescription drug coverage that occurs between the initial coverage limit (as defined in 1860D-2(b)(3)) and the out-of-pocket threshold (as defined in section 1860D-2(b)(4)(B)). For purposes of applying the initial coverage limit, Part D sponsors shall apply their plan specific initial coverage limit under basic alternative, actuarially equivalent, or enhanced alternative Part D benefit designs.

100.7 "Date of Dispensing" means the date of service.

100.8 "Labeler Code" means the first five digits in the 11-digit national drug code (NDC) format that is assigned by the FDA and identifies the Manufacturer (as defined in 100.9)

100.9 "Manufacturer" means any entity which is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include wholesale distributors or retail pharmacies licensed under State law.

100.10 "National Drug Code (NDC)" means the identifying prescription drug product number that is registered and listed with the Food and Drug Administration (FDA). Unless specified in this guidance, the NDC refers to either the 9 digit (inclusive of 5 digit labeler code and 4 digit product code) or 11 digit NDC (inclusive of 5 digit labeler code, 4 digit product code, and 2 digit package size code).

100.11 "Negotiated price" has the meaning given such term in section 42 CFR 423.100 (as in effect on the date of enactment of this section), except that such negotiated price shall not include any dispensing fee for the applicable drug.

100.12 "Part D drug" has the meaning given such term in 42 CFR 423.100.

100.13 "Qualified Retiree Prescription Drug Plan**"** has the meaning given such term in section 1860D-22(a)(2) of the Social Security Act.