DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

DATE: April 30, 2010

TO: All Part D Sponsors

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SUBJECT: Medicare Coverage Gap Discount Program beginning in 2011

The purpose of this memorandum is to provide Part D sponsors with draft guidance for implementing the Medicare Coverage Gap Discount Program (the Discount Program), recently enacted into law in section 3301 of the Patient Protection and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) (PPACA), as amended by section 1101 of the Health Care and Education Reconciliation Act of 2010 (H.R. 4872)(HCERA) 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 Discount Program through program instruction and this memorandum will serve 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. The Centers for Medicare & Medicaid Services (CMS) is issuing this draft guidance for public comment through close of business on May 14, 2010. CMS will issue final guidance after considering all public comments.

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 standalone 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 the greater of $2/$5 or five-percent catastrophic coverage for individuals that exceed the annual maximum true out-of-pocket (TrOOP) threshold. 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 in beginning 2011 for generic drugs and 2014 for applicable drugs as required by section 1860D-2(b), as amended by the HCERA.)

The PPACA, 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 covered Part D drugs while in the coverage gap. In general, the discount on each applicable covered Part D drug is fifty percent of an amount equal to the negotiated price (as defined section 100.13 of this guidance). With the exception of 2011 for reasons discussed later in this guidance, a Part D drug will only be covered under Part D 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 drug spend (GDS) 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, 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 on HPMS on the Part C & D Bid and Premium Information page.

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.

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 provision will ensure that Part D sponsors do not receive duplicate payments for the manufacturer discounts made available to their enrollees.

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 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.

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.

40 Manufacturer discount payments

CMS 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 and reimbursing Part D sponsors.

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 aggregate manufacturer discount amounts reported on the PDE records submitted to CMS during the applicable quarter. The invoices will be itemized at either the 9 digit or 11 digit NDC level as determined by CMS. Manufacturers will be required to pay the invoiced amounts to Part D sponsors directly. Manufacturers must pay the entire invoiced amount within 15 days of receipt including any amounts in dispute. CMS specifically requests comments on this proposed approach for manufacturer payments.

50 Conditions for Coverage under Part D

Beginning January 1, 2011, §1860D-43(a) of PPACA limits Part D coverage to only those Part D 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 Covered Part D Drugs must be covered under a manufacturer agreement.

All covered Part D 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. Only those covered Part D drugs with NDCs that have labeler codes specified in a manufacturer discount agreement may be covered under Part D.

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.

Beginning in 2012, Part D sponsors must provide prospective notice to affected Part D enrollees if a covered Part D drug will no longer be covered for failure of a manufacturer to sign a manufacturer discount agreement. Part D transition requirements will not apply.

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 Part D 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 will inform Part D sponsors if any Part D 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

There are extenuating circumstances in 2011 for all Part D drugs due to the conflict between the timing of 2011 formulary submissions and the signing of manufacturer discount agreements. Part D sponsors must submit their 2011 formularies by April 2010. CMS plans to issue a proposed notice of a Model Manufacturer Agreement for public comment and finalize the model in the July-August timeframe. Given that Part D sponsors could not have known which manufacturers would or would not have discount agreements in effect for 2011 when establishing their formularies, nor could beneficiaries have chosen plans during the annual election period based on this information, CMS must allow coverage in 2011 of Part D drugs irrespective of manufacturer discount agreements. This could mean that some of the brand-name drugs on plan formularies will not be discounted in the coverage gap unless all manufacturers of Part D drugs enter into agreements for 2011 by our deadline in 2010. If this situation occurs, CMS will provide clear public guidance on why discounts are not available for some formulary brand name drugs. Only applicable drugs with labeler codes identified by CMS as having manufacturer discount agreements in place for 2011 shall be discounted in 2011.

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 100.6 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).

Covered Part D drugs covered by a Part D sponsor under transition and emergency fill policies are applicable drugs 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.

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 coverage 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).

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 eliminates the coverage gap (with the exception of routine cost sharing), 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.

Similarly, employer group health and waiver plans (EGHPs & EGWPs) that fill in the coverage gap would be excluded from the Discount Program. Given the extensive waivers that are provided to EGWPs, CMS is unsure of the level of supplemental benefits is provided in the gap, although we predict that most retiree benefit designs would include coverage in the gap. Nevertheless, since CMS is unable to verify the hierarchies of applying supplemental benefits before the discounts based upon the data available to us, CMS is still considering how this requirement will be applied to EGHPs and EGWPs and will provide further guidance in the future. CMS specifically requests comments on this issue.

If a Part D sponsor offers supplemental benefits for applicable drugs in the coverage gap that does not eliminate the coverage gap (with the exception of routine cost-sharing), the applicable discount shall be determined according to the following rule:

The applicable discount is equal to 50% of (the negotiated price in the coverage gap phase minus the supplemental benefits).

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 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)(3)(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/No Retroactivity

Part D sponsors shall use the "date of dispensing," as defined in section 100.8 of this guidance, for purposes of providing a discount at POS and the amount of such discount, if any. Limiting this determination to the "date of dispensing" eliminates the potential for retroactive changes in eligibility (e.g. retroactive changes to low-income status or changes to the benefit-phase in which the claim was adjudicated) for purposes of adjusting the discount. Thus, the status of the claim and beneficiary eligibility on the date of dispensing will be the sole basis for determination of eligibility for the discount and amount of the discount, even if later information retroactively changes effective eligibility back to the date of service.

For example, if on the date that a coverage gap claim is electronically submitted by the pharmacy and adjudicated by the Part D sponsor (i.e. "paid response" returned to the pharmacy) the Part D sponsor does not have information showing low-income subsidy eligibility, the applicable discount shall be applied at POS and shall NOT be adjusted at a later date if more perfect information becomes available. Similarly, if an applicable discount was correctly applied to a claim based upon the information available when the claim was adjudicated to the pharmacy, the discount, or lack thereof, shall not be adjusted when back-end reprocessing claims in order to accommodate late financial information reporting transactions are received by the Part D sponsor.

Nevertheless, if a claim was incorrectly adjudicated by the Part D sponsor as a result of Part D sponsor error, the Part D sponsor shall make retroactive adjustments to the discount, if applicable. These corrections should be offline whenever possible (e.g. through refunds or bills to the beneficiary as opposed to claim reversals). The Part D sponsor must promptly resolve beneficiary complaints and issue payments to beneficiaries on requests for reimbursement within 15 days when the sponsor did not advance the discount at POS due to sponsor error.

70.5 Point-of-sale Exceptions

Part D sponsors shall provide the applicable discount for out-of-network paper claims submitted by Part D enrollees. However, the discount shall not apply to in-network claims that were not submitted electronically by the pharmacy for any reason other than the pharmacy was technically unable to process claims on the date of service through no fault of the beneficiary. This means that beneficiaries that choose to have a prescription filled for a "better cash price" that is not processed through the Part D sponsor will not receive a manufacturer discount under the Discount Program on such prescription.

70.6 Part D compounds

Part D sponsors shall only provide the discount on an applicable drug included in a Part D compound and submitted to CMS on the PDE. The Part D sponsor shall only provide the discount on the applicable drug included in the PDE because only that discount can be reported to CMS and invoiced to a manufacturer. 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 expedite the submission of PDEs to CMS 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 coverage determination 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

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), including authorized generics (as defined in 100.5 of this guidance) 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 provided through an exception or appeal.

100.3 "Applicable Discount" means fifty percent of the portion of the negotiated price (as defined in 100.13) of the applicable drug of a Manufacturer that falls within the coverage gap (as defined in 100.7).

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 "Authorized Generic**"** means a listed drug (as that term is used in 21 USC 355(j)) that:

(A) has been approved under subsection 21 USC 355(c); and

(B) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the listed drug.

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

100.7 "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 or actuarially equivalent Part D benefit designs.

100.8 "Date of Dispensing" means the date the claim was initially adjudicated, more specifically, the date the last "paid response" (as defined in the NCPDP Telecommunication Implementation Guide 5.1) was transmitted to the pharmacy for electronic pharmacy claims (i.e. does not include post-POS adjustments) or date of receipt for all other claims.

100.9 "Incurred Costs**"** has the meaning given such term in 42 CFR 423.100, and includes the negotiated price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Discount Program regardless of whether part of such costs were paid by a manufacturer under such program.

100.10 "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 100.11)

100.11 "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.

100.12 "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).

100.13 "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.

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

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

Please send comments pertaining to this guidance to partdbenefitimpl@cms.hhs.gov with the following subject line "Coverage Gap Discount Program". Comments received by May 14, 2010 will be considered.