What Will Fill the "Donut Hole"? A Summary of the Medicare Part D Coverage Gap Discount Program

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Introduction

This article explains the Medicare Part D Coverage Gap Discount Program (CGDP) created by federal healthcare reform legislation, outlines Centers for Medicare & Medicaid Services (CMS) guidance that has been released regarding the Program, and discusses the new responsibilities of prescription drug manufacturers and Part D Prescription Drug Plan Sponsors under the Program. The article then lays out key issues that manufacturers should consider as they prepare for the Program to go into effect on January 1, 2011.

Overview

Since its inception in 2006, the Medicare Part D prescription drug benefit has included a "coverage gap" (often referred to as the donut hole), which is the phase during which beneficiaries are entirely responsible for the cost of prescription drugs. This coverage gap begins when a beneficiary's true out-of-pocket (TrOOP) expenditures surpass the initial coverage limit (ICL), and it continues until the beneficiary's TrOOP surpasses the catastrophic coverage threshold (CCT).[1] To close this coverage gap over the next ten years, the Patient Protection and Affordable Care Act,[2] as amended by the Health Care and Education Reconciliation Act of 2010[3] (Affordable Care Act or ACA) created the CGDP.[4]

Beginning January 1, 2011, "applicable drugs"[5] will only be eligible for coverage under Part D if their manufacturers agree to participate in the CGDP. Under the CGDP, manufacturers will be required to make discounts available to "applicable beneficiaries"[6] who purchase those manufacturers' "applicable drugs" while in the coverage gap. Generally, these discounts will be 50% of the drug's negotiated price[7] and will be provided at the point-of-sale (POS), i.e., pharmacies. In order to participate in the CGDP, a manufacturer will have to enter into a written agreement with the Secretary of the U.S. Department of Health and Human Services (HHS Secretary), provide discounts on coverage gap claims for *all* of its applicable drugs, and remain in compliance with the terms of the written agreement.

To implement the CGDP, CMS will contract with a third-party administrator (TPA). All manufacturers must also sign an agreement with a TPA as a condition of participation in the CGDP. Through the TPA, CMS will collect discount amounts from manufacturers and then provide those discount amounts to Medicare Part D prescription drug plan sponsors (PDP Sponsors) to reimburse them for the POS discounts provided to patients at the pharmacy and initially paid for by the PDP sponsors.[8] Payments to PDP Sponsors will be based on new information PDP Sponsors submit to CMS on Prescription Drug Event (PDE) records.

Important Implementation Dates

- **April 30, 2010:** CMS issues Draft CGDP guidance for comment.
- **May 21, 2010:** CMS issues Revised CGDP guidance.
- **May 21, 2010:** CMS publishes for comment in the *Federal Register* the Draft Model CGDP Manufacturer Agreement.
- **June 1, 2010:** CMS holds public meeting in Baltimore, MD, to discuss Draft Model CGDP Manufacturer Agreement.
- **July 7, 2010:** CMS releases Draft Model CGDP Third Party Administrator Agreement and Data Use Agreement.
- **August 2, 2010:** CMS posts Final Model CGDP Manufacturer Agreement, Final CGDP Third Party Administrator Agreement, and Final Data Use Agreement to CMS website. Thirty-day signing period commences.
- **September 1, 2010:** Deadline for manufacturers and TPAs to sign agreements and participate in CGDP for 2011.
- **October 1, 2010:** CMS deadline to post on the CMS website and distribute to PDP Sponsors an updated 2011 list of labeler codes that are covered by manufacturer discount agreements.
- **January 1, 2011:** CGDP goes into effect. PDP Sponsors must provide discount at POS.
- **January 30, 2011:** Deadline for manufacturers to enter into or terminate manufacturing discount agreements for 2012. (The Final Model Manufacturer Agreement requires participation in the CGDP for 2011 and 2012, and permits renewal annually beginning in 2013.)

Program Description, Obligations, and Mechanics

The Discount

The discount on each applicable drug will be 50% of its negotiated price, which is a drug-specific amount negotiated between each PDP Sponsor and its network pharmacies. If an applicable beneficiary has a claim for an applicable drug that "straddles" the coverage gap and another phase of the Part D benefit, the discount is applied to only the portion of the negotiated price of the applicable drug that falls both above the ICL and below the CCT.[9] In order words, if a beneficiary's TrOOP is only $25 below the ICL, and the beneficiary has a claim for an applicable drug whose negotiated price was $100, the CGDP discount would be applied to $75 of the claim, i.e., the portion of the claim that actually falls within the coverage gap.

New Part D Coverage Conditions

Beginning January 1, 2011, Part D coverage will be limited only to applicable drugs of a manufacturer that has:

- Agreed to participate in the CGDP;
- Entered into an agreement with CMS to pay discounts under the CGDP; and
- Entered into and has in effect a contract with a CMS' contracted TPA.[10]

PDP Sponsors must provide prospective notice to affected Part D enrollees if a previously covered drug will no longer be covered because of the failure of a manufacturer to sign a manufacturer discount agreement.[11]

There is an exception for drugs that CMS determines are "essential to the health" of Part D enrollees.[12] Although CMS generally expects that all manufacturers of applicable drugs will sign CGDP agreements, CMS will notify PDP Sponsors if it has determined that any applicable drug not covered by a manufacturer agreement is essential for the health of Part D enrollees.[13]

Part D Sponsor Responsibilities and Payment Process

Manufacturer discounts provided under the CGDP must be provided at POS, meaning that the discounts must be credited against the beneficiaries' out-of-pocket costs at the time of purchase.[14] However, discounts could only be applied at POS if the entity adjudicating the claim has the information necessary to determine:

- That the drug is an applicable drug covered by a manufacturer discount agreement;
- That the beneficiary is eligible for a discount;
- That the claim is wholly or partially within the coverage gap; and
- The amount of the discount, taking into consideration plan supplemental benefits[15] that may apply.[16]

CMS has determined that the only entity capable of facilitating the receipt of discounts at POS is the PDP Sponsor because no other entity will have all four items of information.[17] CMS did explore the viability of a model whereby a TPA would directly adjudicate the discount payments to pharmacies, but CMS ultimately opted against this model because of concerns that it would be incompatible with the Health Insurance Portability and Accountability Act standard for electronic pharmacy claims billing.[18]

If a PDP Sponsor offers supplemental Part D coverage, the discount will not be applied until after such supplemental coverage has been applied.[19] Furthermore, if the supplemental coverage already eliminates the coverage gap, manufacturer discounts are not made available.[20] However, PDP Sponsors need to apply the applicable manufacturer discount before any coverage or financial assistance under other health benefit plans or programs (such as AIDS Drug Assistance Programs).[21]

PDP Sponsors are obligated to use the date of dispensing for purposes of providing and determining the amount of the discount.[22] However, if new information subsequently reveals that a claim initially deemed ineligible for a discount actually was eligible, PDP Sponsors must make retroactive adjustments to the applicable discount to reflect the new information.[23] For example, if a claim for an applicable drug was initially adjudicated to be within the initial coverage phase, but the PDP Sponsor later learns that the drug was dispensed during the coverage gap, the applicable discount must be applied to the adjusted claim and collected from the manufacturer. The converse also is true: PDP Sponsors must refund to manufacturers any discounts collected on claims that were originally adjudicated to be within the coverage gap but that later are discovered to have been dispensed during the catastrophic coverage phase.[24]

Collection of discount payments from manufacturers and payment to PDP Sponsors will involve a standard process for paying PDP Sponsors based on new information submitted to CMS on PDE data.[25] Beginning January 1, 2011, PDP 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.[26] PDP Sponsors must also develop and implement processes to account for these amounts separately in order to populate PDE records and Explanation of Benefits forms, as well as to track receivables for reimbursement.[27] PDP Sponsors must reimburse the pharmacy within fourteen days for clean claims submitted electronically and thirty days for clean claims submitted by any other means.[28]

CMS will provide monthly prospective payments to PDP Sponsors for the manufacturer discounts based on the projections in the bid package that each PDP Sponsor submitted to CMS and the PDP's current enrollment, and CMS will estimate the "per member per month" amount of the manufacturer discounts for each PDP based on projected coverage gap drug costs.[29] At the end of the contract year, CMS will reconcile the prospective CGDP payments that the PDP Sponsor received from CMS with the actual manufacturer discount amounts made available to each PDP's enrollees.[30] The actual manufacturer discount amounts will be calculated from the PDP Sponsor's report of the manufacturer discount amounts on the PDE records.[31]

PDP Sponsors will not be required to provide a separate estimate for these manufacturer discount amounts in their PDP bids because, with the exception of potential changes in drug utilization, the CGDP does not affect how drug costs are reported and projected in the Part D bids.[32] PDP Sponsors must include the administrative costs associated with administering the CGDP in the administrative expense component of their Part D bids, but CMS has expressly instructed PDP Sponsors not to include manufacturer discounts in the rebate amounts they reported in their bids.[33]

PDP Sponsors will be required to report manufacturer discounts in a new "Reported Gap Discount" field in the PDE records, and these discounts will be used for the cost-based reconciliation of the prospective CGDP payments made to each Part D sponsor.[34]

Manufacturer Obligations

On August 2, 2010, CMS released the Final Model CGDP Manufacturer Agreement (Final CGDP Agreement).[35] Manufacturers should be aware of several items included in the Final CGDP Agreement.

Invoicing, Payment, and Penalties

Under the Final CGDP Agreement, the manufacturer will receive from CMS or its TPA on a quarterly basis invoices that include "Medicare Part D Discount Information"[36] and summarize the total units dispensed and total discounts paid by each PDP Sponsor for the manufacturer's applicable drugs.[37] Interestingly, these invoices can include the "applicable discounts" for an "applicable drug" up to three years after the date of dispensing.[38]

Consistent with the Medicaid Drug Rebate Program's payment timeframe, the manufacturer must pay the invoiced amounts within thirty-eight days.[39] Payments will be made electronically to accounts established by PDP Sponsors.[40] The manufacturer must provide CMS and the TPA with documentation "in a manner specified by CMS" showing that the payment transmission was successful.[41] Should the manufacturer fail to provide payment within thirty-eight days, the HHS Secretary may impose a civil monetary penalty on the manufacturer equal to the amount of the invoiced discounts plus an additional 25%.[42]

Audits

Under the Final CGDP Agreement, both the manufacturer and the HHS Secretary have the right to conduct annual audits.[43] Several PDE cost elements are available to the manufacturer to validate discount calculations only upon audit,[44] and these data elements will be available only for a "significant sample size of PDEs."[45] Furthermore, the manufacturer is limited under the Final CGDP Agreement to auditing the data and information made available by the TPA and is not permitted to audit CMS records or the records of Part D sponsors.[46] CMS also has explicitly stated that it will not provide any beneficiary identifiable information, even upon audit.[47]

The HHS Secretary, on the other hand, has the right to audit the "appropriate data" that the manufacturer is required to maintain to demonstrate compliance.[48] Under the Final CGDP Agreement, the manufacturer must maintain for a period of at least ten years "appropriate data"[49] to demonstrate compliance with CGDP requirements.[50] Note that under the Final CGDP Agreement, the PDP Sponsor has no audit rights.

Dispute Resolution

The Final CGDP Agreement is particularly noteworthy for its provisions relating to disputes by the manufacturer regarding discounts provided under the CGDP. Many other government discount or rebate programs for prescription drugs, such as the Medicaid Drug Rebate Program and the TRICARE Retail Pharmacy Program, permit manufacturers to withhold payments for disputed amounts pending resolution. Under the Final CGDP Agreement, however, if the manufacturer disputes an invoiced payment, the manufacturer is not permitted to withhold such payment except for those invoiced amounts for drugs that the manufacturer disputes are subject to the agreement.[51] When the Draft CGDP Manufacturer Agreement was released, manufacturers requested that they be allowed to refuse to pay discount amounts that were clearly erroneous or that they disputed in good faith. CMS ultimately objected to the request, however, reasoning that "PDE data has been subject to numerous controls prior to being submitted to the government and . . . CMS will be performing extensive editing on the data prior to invoicing manufacturers."[52]

To resolve a dispute, the manufacturer must provide written notice of the disputed discounts, on a drug-by-drug basis, to CMS and its TPA within sixty days of receipt of the invoice containing the disputed discount claim.[53] The information provided must be "material, specific, related to the dispute at issue, and have evidentiary support."[54] The manufacturer and TPA are required to "use their best efforts" to resolve the dispute within sixty days of receipt of the dispute notification.[55] If the dispute is not resolved within sixty days, CMS will independently review the dispute and make a determination.[56] If the manufacturer disagrees with CMS' determination, the manufacturer may request review by the CMS Administrator.[57] The decision by the CMS Administrator is final and binding, with no additional right to appeal specified.[58] Notably, if the manufacturer prevails in the dispute, the Final CGDP Agreement does not specify how the disputed amount would be refunded.

TPA Agreements

In order to participate in the CGDP, a manufacturer must enter into and have in effect an agreement with the TPA that contracts with the Secretary to administer the CGDP.[59] CMS released the Final CGDP Third Party Administrator Agreement (Final GCDP TPA Agreement) when it released the Final CGDP Manufacturer Agreement. Under the Final GCDP TPA Agreement, the manufacturer must establish and maintain a point of contact responsible for establishing and maintaining connectivity between the manufacturer and the TPA.[60] The manufacturer must also provide electronic connectivity to send and receive Medicare Part D Discount Information to and from the TPA using CMS-approved record formats,[61] and the manufacturer and

TPA must employ certain security measures prior to transmitting any data.[62]

Furthermore, according to the Final GCDP TPA Agreement, prior to the initial exchange of discount information between the TPA and the manufacturer, the manufacturer and the TPA must perform testing to "ensure the accuracy, timeliness, completeness and confidentiality" of each data transmission.[63] This testing must begin at least ninety days prior to the first data transmission and end at least thirty days prior to the first data transmission.

Program Oversight

PDP Sponsors will be required to handle beneficiary inquiries and complaints about the CGDP and to resolve all beneficiary questions and concerns.[64] However, beneficiaries will also have access to the existing Part D coverage determination and appeals process for disputes involving manufacturer discounts.[65] CMS will periodically analyze PDE data submissions in which PDP Sponsors will be required to specify whether a discount was provided on a claim and, if so, the amount of that discount.[66] Finally, CMS will use its complaint tracking protocol to monitor beneficiary complaints related to the CGDP and will establish metrics to monitor its effect.[67]

Contracting Considerations for Manufacturers

As the effective date for the CGDP approaches, the following are some key issues that manufacturers should consider as they prepare for implementation.

- Participation in the CGDP (through execution of a CGDP Agreement) only ensures that a manufacturer's drugs remain eligible for Part D coverage. Manufacturers must still negotiate with PDP Sponsors to have their drugs included on those PDPs' formularies (or otherwise covered by the PDPs), and formulary agreements generally require manufacturers to pay rebates to PDP Sponsors on utilization of their drugs by those PDPs' enrollees.
- If a manufacturer currently does not have any applicable drugs, signing the CGDP Agreement does not impose any discount requirements on that manufacturer. However, if such a manufacturer does not sign the CGDP Agreement by the required deadline and later does determine that one of its products is an applicable drug, the manufacturer will not be able to participate in the CGDP until the following year. In the meantime, any products of the manufacturer would not be covered under Part D. Therefore, even if a manufacturer believes that it does not market any applicable drugs, caution dictates signing the CGDP Agreement.
- The discounts that manufacturers will pay under the CGDP will be based on the prices for their drugs that are negotiated between PDP Sponsors and their network pharmacies. Manufacturers, therefore, will be paying discounts on prices they have no role in negotiating. Manufacturers should consider, at a minimum, including requirements for the PDP Sponsors to disclose the negotiated prices for their applicable drugs, for planning purposes.
- Manufacturers' CGDP discounts will be distinct from rebates that they agree to pay to PDP Sponsors pursuant to individually negotiated formulary agreements. Historically, it has not been unusual for these formulary agreements to require rebates to be paid on drugs dispensed to PDP enrollees during the coverage gap, even though the PDP Sponsors are not then incurring costs. Therefore, under formulary agreements such as these, manufacturers would pay both CGDP discounts and formulary rebates on the same utilization during the coverage gap. Moreover, the negotiated prices on which CGDP discounts will be based, by definition, will not be reduced by the rebates that manufacturers pay to PDP Sponsors under formulary agreements. This could ultimately result in manufacturers paying significant aggregate price concessions on coverage gap utilization, perhaps even in excess of the prices at which the manufacturers sold the drugs. Manufacturers should review their existing formulary agreements to determine the potential impact of their current rebate obligations on the revenue generated by drugs dispensed during the coverage gap, in combination with CGDP discounts, and consider seeking revisions to their formulary agreements if necessary.
- Finally, in considering the overall financial impact the CGDP will likely have, manufacturers also should consider near- and long-term trends in Medicare enrollment. Medicare enrollment projections by the CMS Office of the Actuary forecast the number of Medicare beneficiaries nearly doubling by 2030. In large part, this dramatic increase reflects the impact of a large increase in beneficiaries starting in 2010 as the leading edge of the baby boom generation reaches age sixty-five and becomes eligible to receive benefits.

Conclusion

The CGDP will impose significant new responsibilities upon pharmaceutical manufacturers and will create additional obligations for PDP Sponsors as well. In addition to these obligations, the expectation is that the CGDP will also provide opportunities, particularly as the Medicare population expands dramatically over the next twenty years. Who reaps the benefits of that expansion will depend to some extent on those parties' contracting strategies and the outcome of their negotiations for formulary and rebate agreements. Consequently, manufacturers should prepare not only for compliance with the CGDP requirements but also for strategic contracting that will ensure that they secure the opportunity, and not just the obligations, created by this new Program.

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1 For 2011, the ICL will be $2,840, and the CCT will be $4,550. *See* CMS Memorandum, "Announcement of Calendar Year (CY) 2011 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter" (Apr. 5, 2010), at 34.

2 Pub. L. No. 111-148, Section 3301, 124 Stat. 119 (2010) (PPACA).

3 Pub, L. No. 111-152, Section 1101, 124 Stat. 1029 (2010) (HCERA).

4 The CGDP is primarily codified at Sections 1860D-14A of the Social Security Act (SSA).

5 An "applicable drug" is a prescription drug or biologic that is either approved under a new drug application 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 (other than a product licensed under subsection (k)) and that is covered by an applicable beneficiary's Part D prescription drug plan, either on its formulary or otherwise. *See* PPACA Section 3301(b), 124 Stat. 119, 466, *codified at* SSA Section 1860D-14A(g)(2), 42 U.S.C. § 1395w-114(A). Therefore, the CGDP will apply to "innovator" or "brand name" prescription drugs and biologics. "Generic" prescription drugs and biologics (i.e., biosimilars) will not be within the CGDP's scope.

6 An "applicable beneficiary" is an individual who, on the date a covered Part D drug is dispensed: (1) is enrolled in a Medicare Part D prescription drug plan or a Medicare Advantage (i.e., Medicare Part C) prescription drug plan; (2) is not enrolled in a qualified retiree prescription drug plan; (3) is not entitled to an income-related subsidy under Section 1860D-14(a) of the SSA; (4) has reached or exceeded the ICL under Section 1860D-2(b)(3) of the SSA during the year; and (5) has not surpassed the catastrophic coverage threshold specified in Section 1860D-2(b)(4)(B) of the SSA. *See* PPACA Section 3301(b), 124 Stat. 119, 466, *codified at* SSA Section 1860D-14A(g)(1), 42 U.S.C. § 1395w-114(A).

7 "Negotiated price" is the price that is available to beneficiaries at the POS at network pharmacies and is reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the POS. The negotiated price does not include any dispensing fee. *See* PPACA Section 3301(b), 124 Stat. 119, 467, *codified at* SSA Section 1860D-14A(g)(6), 42 U.S.C. § 1395w-114(A); *see also* 42 C.F.R. § 423.100.

8 Throughout this article, references to "PDP Sponsors" include not only sponsors of stand-alone Part D prescription drug plans, but also sponsors of Medicare Advantage plans that provide the Medicare Part D prescription drug benefit.

9 *See* PPACA Section 3301(b), 124 Stat. 119, 467, *codified at* SSA Section 1860D-14A(g)(4)(C), 42 U.S.C. § 1395w-114(A); *see also* CMS, Memorandum, "Medicare Coverage Gap Discount Program Beginning in 2011: Revised Part D Sponsor Guidance and Responses to Summary Public Comments on the Draft Guidance (May 21, 2010) [CMS Sponsor Guidance], at 21.

10 *See* PPACA Section 3301(a), 124 Stat. 119, 461, *codified at* SSA Section 1860D-43(a), 42 U.S.C. § 1395w-153; *see also* CMS Sponsor Guidance at 15-16.

11 *See id.*

12 *See* PPACA Section 3301(a), 124 Stat. 119, 461, *codified at* SSA Section 1860D-43(c), 42 U.S.C. § 1395w-153; *see also* CMS Sponsor Guidance at 16.

13 *See* CMS Sponsor Guidance at 16.

14 *See* PPACA Section 3301(b), 124 Stat. 119, 463, *codified at* SSA Section 1860D-14A(c)(1)(A)(ii), 42 U.S.C. § 1395w-114(A); *see also* CMS Sponsor Guidance at 11.

15 Some Part D prescription drug plans already provide partial or complete coverage during the coverage gap, usually in exchange for the beneficiary paying a higher premium.

16 *See* CMS Sponsor Guidance at 11.

17 *See id.* at 12.

18 *See id.*

19 *See* PPACA Section 3301(b), 124 Stat. 119, 464, *codified at* SSA Section 1860D-14A(c)(2), 42 U.S.C. § 1395w-114(A); *see also* CMS Sponsor Guidance at 18.

20 *See* CMS Sponsor Guidance at 18.

21 *See id.*

22 *See id.* at 19.

23 *See id.*

24 *See id.*

25 *See id.* at 15.

26 *See id.* at 12.

27 *See id.*

28 *See id.* at 22.

29 *See id.*

30 *See id.* at 13.

31 *See id.*

32 *See id.*

33 *See id.*

34 *See id.*

35 *See* Medicare Coverage Gap Discount Program Agreement between the Secretary of the U.S. Department of Health and Human Services and the Manufacturer Identified in Section X of this Agreement, Aug. 2, 2010, *available at* www.cms.gov/PrescriptionDrugCovGenIn/Downloads/ManuAgreement.pdf (Final Manufacturer CGDP Agreement).

36 *See id.* at pt. I(k). The data elements included in "Medicare Part D Discount Information" are: Date of Service, Service Provider Identifier Qualifier, Service Provider Identifier, Prescription/Service Reference Number, Product/Service Identifier, Quantity Dispensed, Days Supply, Fill Number, and Reported Gap Discount. This information will be derived from applicable data elements available on the PDEs as determined by CMS.

37 *See id.* at pt. II(a).

38 *See id.*

39 *See id.* at pt. II(b).

40 *See id.* at pt. II(m).

41 *See id.*

42 *See id.* at pt. IV.

43 *See id.*

44 *See id.* at Exhibit B. The PDE costs elements available upon audit only include: contract number, plan benefit package identifier, ingredient cost paid, dispensing fee paid, total amount attributed to sales tax, law-income cost-sharing amount, non-covered plan amount, vaccine administration fee, and the two new PDE fields identified as "Total Cross Covered Drug Cost Accumulator" and "True Out-of-Pocket Accumulator."

45 *See id.* at pt. V(c).

46 *See id.*

47 *See* CMS Memorandum, "Medicare Coverage Gap Discount Program—Manufacturer Agreements (Aug. 3, 2010) (CMS Final Manufacturer Agreement Memorandum) at 2.

48 *See* Final Manufacturer CGDP Agreement at pt. V(c).

49 *See id.* at pt. II(d). "Appropriate data" includes data related to the manufacturer's labeler codes, expiration date of national drug codes, utilization and pricing information relief on the by manufacturer to dispute quarterly invoices, and "any other data the Secretary determines are necessary to carry out [the CGDP]."

50 *See id.* at pt. V(a).

51 See *id.* at pt. V(f).

52 *See* CMS Final Manufacturer Agreement Memorandum at 2.

53 *See* Final Manufacturer CGDP Agreement at pt. V(e).

54 *See id.*

55 *See id.* at pt. V(g).

56 *See id.*

57 *See id.*

58 *See id.*

59 *See* Final Manufacturer CGDP Agreement at pt. II(l).

60 *See* Medicare Coverage Gap Discount Program Agreement between Third Party Administrator and the Manufacturer Identified in Section VIII of this Agreement, Aug. 2, 2010, *available at* www.cms.gov/PrescriptionDrugCovGenIn/Downloads/TPAAgreement.pdf (Final TPA CGDP Agreement) at pt. II(a).

61 *See* Final TPA CGDP Agreement at pt. II(b), (c).

62 *See* Final TPA CGDP Agreement at pt. IV(c), (d).

63 *See* Final TPA CGDP Agreement at pt. IV(a), (b).

64 *See* CMS Sponsor Guidance at 20.

65 *See id.*

66 *See id.*

67 *See id.*