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CENTER FOR MEDICARE

TO: Part D Sponsors and Pharmaceutical Manufacturers

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SUBJECT: Medicare Coverage Gap Discount Program—Maximum Applicable Discounts
Updates

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On January 27, 2012, the Centers for Medicare & Medicaid Services (CMS) issued a Health Plan Management System (HPMS) memorandum titled, “Medicare Coverage Gap Discount Program—Maximum Applicable Discounts”. This guidance explained how the applicable discount amounts specified on the claims-level detail reports provided with the quarterly invoice can be evaluated by manufacturers. The document used examples to illustrate how different benefit designs and supplemental insurance contributed to CMS’ establishment of maximum allowable manufacturer discount amounts for 2011 and 2012. We are now updating our guidance to explain how the incremental closing of the coverage gap with increasing coverage under the basic Part D benefit until 2020 changes how maximum allowable manufacturer discounts under the Medicare Coverage Gap Discount Program (Discount Program) are calculated. Because Part D sponsors will share a portion of the negotiated price, remaining True Out-of-Pocket Threshold (TrOOP) cannot be used to determine the maximum possible gap discount amount for a single claim.

To clarify, the definition of the applicable discount, as defined in the manufacturer’s agreement has not changed. Part D sponsors are responsible for ensuring that manufacturers are invoiced only for the applicable discount, which is defined as 50 percent of the portion of the negotiated price of the applicable drug of a manufacturer that falls within the coverage gap. Part D sponsors are expected to follow existing PDE guidance for calculating and reporting the Reported Gap Discount amount, this guidance includes the July 9, 2010 HPMS memorandum titled, “Revised Guidance for Prescription Drug Event (PDE) Record Changes Required to Close the Coverage Gap”, the 2011 Regional Prescription Drug Event Technical Assistance Participant Guide, the 2013 PDE Reporting and Calculations guidance, and the 2014 PDE Reporting and Calculations guidance. CMS is releasing this update to the January 27, 2012 guidance to clarify the maximum discount dollar amounts that may be invoiced to the manufacturer regardless of the benefit design. This guidance does not change or impact the way sponsors are expected to calculate and report the Reported Gap Discount Amount.

Background

The Part D benefit parameters for defined standard coverage are established annually in accordance with statutory requirements. The Affordable Care Act which established the Discount Program also gradually increased Medicare gap coverage for applicable drugs. Between 2013 and 2020, basic Part D coverage for applicable drugs will gradually increase with a corresponding decrease in beneficiary cost sharing.

In 2013 and 2014, the beneficiary pays 47.5% of the negotiated price of applicable drugs, the Part D plan pays 2.5%, and the pharmaceutical manufacturer pays 50% in the coverage gap. By 2020, the beneficiary portion will decrease to 25%, the Part D plan will pay 25%, and the pharmaceutical manufacturer will continue to pay 50% of the negotiated price of applicable drugs in the coverage gap. The table below illustrates the percentage of coverage from 2012, and the changes that will occur in between 2013 and 2020 within the coverage gap for applicable drugs.

	2012	2013	2014	2015	2016	2017	2018	2019	2020
Beneficiary pays	50%	47.5%	47.5%	45%	45%	40%	35%	30%	25%
Part D Plan cost sharing	0%	2.5%	2.5%	5%	5%	10%	15%	20%	25%
Manufacturer discount	50%	50%	50%	50%	50%	50%	50%	50%	50%

While total Part D drug costs move a beneficiary into the coverage gap, only true out-of-pocket (TrOOP) costs move the beneficiary towards the annual out-of-pocket threshold. Per CMS guidance sponsors report the additional Medicare Coverage as CPP¹.

Determining the Maximum Discount

Single Claim:

Our prior guidance stated that for 2011 and 2012 dates of service, the maximum allowable discount on a single claim was 50% of the applicable year's TrOOP. This statement was true for 2011 and 2012 because the negotiated price in the coverage gap and remaining TrOOP were the same when determining the maximum discount amount. Both the patient pay amount and reported gap discount amounts are both TrOOP eligible. However, since Medicare Part D plans began to provide coverage in the gap under the basic Part D benefit beginning in 2013, and these dollars do not count towards TrOOP, the maximum discount amounts need to be modified to account for the additional gap coverage.

¹ Prescription Drug Event (PDE) reporting examples for benefit year 2014 from December 2013 posted at [http://www.csscooperations.com/internet/cssc3.nsf/files/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf/\\$File/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf](http://www.csscooperations.com/internet/cssc3.nsf/files/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf/$File/2014%20PDE%20Reporting%20Guidance%2012-13-2013.pdf)

The revised maximum discount formula incorporates both the annual TrOOP amounts as well as the gradual increase in basic Part D coverage in the coverage gap. For example, in 2013 TrOOP is \$4750 and the Medicare plan covers 2.5% of the negotiated drug costs. Therefore, the maximum manufacturer discount is \$2435.90 [(\$4750 ÷ .975) X .50].

The formula starts with remaining TrOOP and is divided by the cost-sharing percentages of the beneficiary and the manufacturer to determine the negotiated price that coincides with remaining TrOOP. Once this amount is determined, then the cost-sharing portions for the manufacturer, beneficiary, and plan can be calculated.

For 2014, TrOOP decreases to \$4550 and coverage for applicable drugs remains at 2.5%. Therefore, the maximum possible discount on a single claim is \$2333.33 [(\$4550 ÷ .975) X .50]).

These examples illustrate that beginning in 2013, due to the additional Medicare contribution to drug costs in the gap, the maximum discount for a single claim is to be calculated as follows:

$$\text{TrOOP dollar amount} \div (\text{beneficiary} + \text{manufacturer gap payment percentages}) \times .50$$

This formula can be broken down into two steps:

1. Determine the negotiated price associated with a beneficiary's remaining TrOOP:

$$\text{TrOOP dollar amount} \div (\text{beneficiary} + \text{manufacturer gap payment percentages}) = \text{gap eligible portion of negotiated price}$$

2. Determine the manufacturer's portion of the negotiated price:

$$\text{Gap Eligible Portion of Negotiated Price} \times .50 = \text{gap discount}$$

Multiple Claims:

As we discussed in our prior guidance, the maximum discount that a beneficiary can receive during a plan year from multiple coverage gap claims depends upon the availability of secondary payers and the TrOOP status of such payers. Nonetheless, the maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is the applicable year's TrOOP. TrOOP was \$4750 in 2013 and is \$4550 in 2014.

For examples of how discounts are calculated under different benefit designs or with supplemental benefits, manufacturers should consult other documents including the January 2012 guidance referenced above, the PDE guidance referenced above, or Chapter 5 of the Medicare Prescription Drug Benefit manual for additional information on qualified prescription drug coverage and TrOOP costs under the Part D program. If after reviewing those documents you have any further questions about the Part D coverage gap and how applicable discounts are determined under the Discount Program, please direct them to CGDPandmanufacturers@cms.hhs.gov.