DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

TO: Pharmaceutical Manufacturers

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

SUBJECT: Medicare Coverage Gap Discount Program—Maximum Applicable Discounts

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Under the Medicare Coverage Gap Discount Program (Discount Program), manufacturers are required to provide beneficiaries with discounts on the negotiated price of applicable drugs. Applicable beneficiaries are Part D enrollees that do not receive income related subsidies under section 1860D-14(a) of the Social Security Act (the Act), have reached or exceeded the initial coverage limit (ICL) under section 1960D-2(b)(3) of the Act, and have not incurred costs for covered Part D drugs in the year equal to the annual out-of-pocket threshold specified in 1860D-2(b)(4)(B) of the Act. In short, manufacturers must provide the discounts on the portion of a claim that falls in Medicare Part D coverage cap (coverage gap).

We have received questions from manufacturers related to how the applicable discount amounts specified on the claims-level detail reports provided with the quarterly invoice were determined. In order to address these questions, we are providing the following guidance to further explain the coverage gap and the potential range of discounts that applicable beneficiaries can receive under the Discount Program.

Understanding the Coverage Gap

The Part D benefit parameters for defined standard coverage are established annually in accordance with statutory requirements. In 2011, the defined standard coverage includes a $310 deductible, 25 percent cost-sharing between the deductible and ICL, a $2840 ICL, and an out-of-pocket threshold of $4550. Under this benefit design, a beneficiary would have incurred $942.50 in out-of-pocket spending when they reach the ICL. Therefore, the beneficiary would have $3607.50 remaining in out-of-pocket spending before reaching the annual out-of-pocket threshold. In other words, they would have a $3607.50 coverage gap remaining before catastrophic coverage begins.

Nevertheless, most Part D plans do not offer defined standard coverage. Part D sponsors frequently provide benefits that are actuarially equivalent to the defined standard coverage or enhanced with lower (or zero dollar) deductibles and fixed copays instead of 25% co-insurance before the ICL. In some cases, Part D sponsors have a lower than standard ICL. Consequently, beneficiaries will have incurred different levels of out-of-pocket spending when the reach the ICL depending upon their specific Part D plan benefit parameters. This means that beneficiaries could have more or less out-of-pocket spending remaining before they reach the annual out-of-pocket threshold or said differently, beneficiaries can have more or less than the $3607.50 coverage gap remaining. For example, if a beneficiary was enrolled in a plan that had zero deductible and $45 copay on a drug that costs $2840, the beneficiary would have a $4510 coverage gap remaining before catastrophic coverage if that was the beneficiary's initial claim. Theoretically, the maximum potential coverage gap in 2011 is $4550 if a beneficiary reached the ICL without having incurred any out-of-pocket spending.

2011 Part D Benefit Design Examples (for Illustration Only)

Benefit Parameters	Defined Standard Coverage	Basic Alternative Coverage	Enhanced Alternative Coverage
Deductible	$310	$150	$0
Brand cost-sharing between deductible and ICL	25%	Preferred $45 Non-Preferred $95 Specialty 25%	Preferred $25 Non-Preferred $45 Specialty 25%
Initial Coverage Limit (ICL)	$2840	$2840	$2840
True Out-of-Pocket (TrOOP) Threshold	$4550	$4550	$4550
Remaining OOP spending to reach TrOOP threshold when beneficiary reaches ICL **(i.e. the coverage gap)**	$3607.50	Less than $4550; Remaining OOP dependent upon specific copays incurred.	Less than $4550; Remaining OOP dependent upon specific copays incurred.
Total Covered Drug Spend at OOP Threshold	$6440	Dependent upon remaining OOP when beneficiary reaches ICL	Dependent upon remaining OOP when beneficiary reaches ICL

The following illustrates how a beneficiary's coverage gap would differ among these three benefit examples for an initial claim for $2840:

Defined Standard Coverage Example: Beneficiary would pay $310 deductible plus (25% of $2530) =$942.50. This means the remaining coverage gap before the beneficiary reaches the $4550 TrOOP threshold would be $3607.50 ($4550 minus $942.50).

Basic Alternative Coverage Example (Non-preferred brand): Beneficiary would pay $150 deductible plus $95 copay = $245. This means the remaining coverage gap before the beneficiary reaches the $4550 TrOOP threshold would be $4305 ($4550 minus $245).

Enhanced Alternative Coverage Example (Non-preferred brand): Beneficiary would pay $45 copay. This means the remaining coverage gap before the beneficiary reaches the $4550 TrOOP threshold would be $4505 ($4550 minus $45).

While total Part D drug costs gets a beneficiary into the coverage gap, only out-of-pocket costs incurred by the beneficiary, or counted as if incurred by the beneficiary, move the beneficiary towards the annual out-of-pocket threshold. These costs are referred to as true out-of-pocket (TrOOP) costs. In addition to the beneficiary payments, state pharmaceutical assistance programs (SPAP) payments, AIDS Drug Assistance Program (ADAP) payments, Indian Health Service (IHS) payments, and manufacturer discount payments under the Discount Program all counts towards TrOOP and move the beneficiary towards the annual out-of-pocket threshold. Notably, however, payments made by secondary payers other than SPAPs and ADAPs do not count towards TrOOP and do not advance a beneficiary through the coverage gap. For example, if a beneficiary had $2000 in out-of-pocket spending remaining in the coverage gap, had a claim for $1000 of which $950 was paid by a non-TrOOP eligible secondary payer, the beneficiary would only advance $50 towards the annual out-of-pocket threshold and still have a $1950 coverage gap remaining.

Please refer to 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.

Determining the Applicable Discount

Single Claim

In 2011, the maximum possible discount on a single claim in is $2275 (or 50% of $4550). The maximum coverage gap will increase to $4700 in 2012 and, therefore, the maximum possible discount on a single claim in 2012 will be $2350 (or 50% of 4700).

An applicable discount is equal to fifty percent of the portion of the negotiated price (as defined in 42 CFR 423.100 but excluding any dispensing fee) of an applicable drug of a manufacturer that falls within the coverage gap. The coverage gap, as discussed above, more often will not be equivalent to the defined standard coverage gap of $3607.50 and could potentially be as much as $4550 if a beneficiary reached the ICL without having incurred any out-of-pocket spending.

Using the coverage gap examples above, the following illustrates how the discount would differ under each benefit design:

Defined Standard Coverage Example: Beneficiary coverage gap is $3607.50. The maximum possible applicable discount would be 50% of $3607.50 = $1803.75[1].

Basic Alternative Coverage Example (Non-preferred brand): Beneficiary coverage gap is $4305. The maximum possible discount would be 50% of $4305 = $2152.50.

Enhanced Alternative Coverage Example (Non-preferred brand): Beneficiary coverage gap is $4505. The maximum possible discount would be 50% of $4505 = $2252.50.

Multiple Claims

In 2011, the maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is $4550. The maximum coverage gap will increase to $4700 in 2012 and, therefore, the maximum aggregate applicable discount amount from multiple coverage gap claims in 2012 will be $4700.

Unlike the maximum discount on a single claim, 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. If a beneficiary does not have any secondary coverage, then the maximum annual discount will be 50% of the maximum coverage gap (same as for a single claim). In 2011 this is $2275 and in 2012 it will be $2350. The maximum discount does not change if payments made by other TrOOP eligible payers such as SPAPs, ADAPs, IHS and manufacturers under the Discount Program.

However, if a secondary payer does not have TrOOP eligible status, then the payments it makes do not count towards TrOOP and do not move the beneficiary towards the out-of-pocket threshold. Consequently, this can increase the total discount that a beneficiary could receive during a plan year by extending the time it takes a beneficiary to move through the coverage gap. For example, if a beneficiary in the coverage gap has $2000 remaining in TrOOP to reach the out-of-pocket threshold and has an applicable drug claim for $2000. The Part D plan will apply the discount to $2000 (less the dispensing fee). The remaining fifty percent would then be billed to the non-TrOOP eligible payer that pays everything except for $50 copay. Since the secondary payer's payment does not count towards TrOOP, the beneficiary only moves towards the annual out-of-pocket threshold by $50 plus the discount paid by the manufacturer. When the next claim is processed, the beneficiary would still have approximately $950 remaining in the coverage gap that would be subject to future discounts for applicable drugs. In theory, if a non-TrOOP eligible secondary payer paid 100% of the beneficiary cost-sharing from the first dollar, the discounts from a manufacturer (or manufacturers) could total the entire coverage gap.

If 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.

[1] In these examples, the dispensing fee assumed to be included in the catastrophic phase of the benefit in accordance with section 70.3 on "Straddle" claims in the May 21, 2010 Discount Program guidance.