DEPARTMENT OF HEALTH & HUMAN SERVICES
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CENTER FOR MEDICARE

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TO: Pharmaceutical Manufacturers and Part D sponsors

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SUBJECT: Updates to the Coverage Gap Discount Program (CGDP)

The purpose of this memorandum is to inform pharmaceutical manufacturers and Part D sponsors of two upcoming changes to the Medicare Part D Coverage Gap Discount Program (CGDP). These modifications are required by Public Law No. 115-123, also known as the Bipartisan Budget Act of 2018 (BBA), enacted on February 9, 2018. This document also discusses operational changes that will be made as a result of the changes described in the BBA. CMS will update our regulations, the CGDP manufacturer agreement, and sub-regulatory guidance as necessary to comply with these statutory requirements.

Manufacturer Discounts:

For costs falling in the coverage gap phase for applicable drugs, the BBA increases the manufacturer discount from 50 to 70 percent[1] and reduces beneficiary cost sharing to 25 percent in 2019 and in future years. Manufacturer discount amounts will continue to count towards a beneficiary's true out-of-pocket cost (TrOOP).

For non-applicable drugs, the law does not change the existing schedule that finishes closing the coverage gap in 2020.

The cost sharing values for current and future years are as follows:

Year	**Applicable Drugs***			**Non Applicable Drugs**		
	Manufacturer Discount	*Beneficiary Cost Sharing*	*Plan Cost Sharing*	*Manufacturer Discount*	*Beneficiary Cost Sharing*	*Plan Cost Sharing*
2018	50%	35%	15%	N/A	44%	56%

[1] Public Law No. 115.-123, Section 53116

Year	Applicable Drugs*			Non Applicable Drugs		
	Manufacturer Discount	*Beneficiary Cost Sharing*	*Plan Cost Sharing*	*Manufacturer Discount*	*Beneficiary Cost Sharing*	*Plan Cost Sharing*
2019	70%	25%	5%		37%	63%
2020 and Beyond	70%	25%	5%		25%	75%

*When the dispensing fee falls within the coverage gap phase for applicable drugs, the beneficiary will pay 25 percent of the dispensing fee and the plans will pay 75 percent of the dispensing fee in 2019 and in future years.

Maximum Discounts:

In the April 30, 2010 HPMS memorandum titled, "Prescription Drug Event (PDE) Record Changes Required to Close the Coverage Gap," CMS introduced the term Discount Eligible Cost. The Discount Eligible Cost is the cost falling in the coverage gap, excluding supplemental benefits and dispensing fee. In that guidance, the gap discount was calculated as the Discount Eligible Cost multiplied by .5. Now that the manufacturer discount is increasing for years 2019 and beyond, the gap discount will be calculated as the Discount Eligible Cost multiplied by .7. There are several Prescription Drug Event (PDE) edit codes that evaluate the Reported Gap Discount amount reported on the PDE. CMS will update the logic used in the calculations associated with these edit codes to account for the 70 percent manufacturer discount starting in 2019. For years 2011 through 2018, the existing logic will use 50 percent as the manufacturer discount. The manufacturer discount is also considered when reviewing outlier PDEs and manufacturer disputes, and therefore calculations within these processes will account for the percentage change.

In the January 27, 2012 HPMS memorandum titled, "Medicare Coverage Gap Discount Program – Maximum Applicable Discounts," CMS provided guidance to further explain the coverage gap and the potential range of discounts that applicable beneficiaries can receive. Within this guidance, CMS explained how to determine the maximum gap discount on a single claim and the maximum aggregate applicable discount for multiple coverage gap claims. CMS updated this guidance in the March 4, 2014 HPMS memorandum titled, "Medicare Coverage Gap Discount Program – Maximum Applicable Discounts Updates," 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. Now that the manufacturer discount percentage and the plan liability are changed beginning in 2019, we are updating those calculations.

The maximum discount for a single claim with a date of service in 2019 and beyond is to be calculated as follows:

(TrOOP dollar amount ÷ (beneficiary + manufacturer gap payment percentages)) X .70

This formula can be broken down into two steps:

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

TrOOP dollar amount ÷ (beneficiary + manufacturer gap payment percentages) = gap eligible portion of negotiated price

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

Gap Eligible Portion of Negotiated Price x .70 = gap discount

As before, the maximum aggregate applicable discount amount that a beneficiary could receive from multiple coverage gap claims is the applicable year's TrOOP.

Biosimilar Drugs:

Currently, biosimilars are excluded from the definition of applicable drugs under the Coverage Gap Discount Program. Section 53113 of the BBA sunsets that exclusion as of January 1, 2019.[2] As a result, for CY 2019 and beyond, biosimilars will be subject to a 70 percent manufacturer discount and must be covered under a CMS CGDP agreement in order to be covered by Medicare Part D.

PDE records submitted for biosimilar drugs with dates of service prior to January 1, 2019, will not be subject to the CGDP requirements. CMS will update PDE editing logic later this year to include biosimilar drugs when considering PDEs with Reported Gap Discount amounts for benefit years 2019 and beyond.

The FDA began publishing the Purple Book in September 2014. It lists biological products, including any biosimilar and interchangeable biological products, licensed by the FDA. Information on biosimilar approvals can be obtained from the Purple Book. The approved application number can then be referenced on the FDA's NSDE file to obtain the NDCs listed for that approved biosimilar.

Questions related to the operational changes that will be made to the Drug Data Processing System can be submitted to PDEJan2011@cms.hhs.gov.

[2] See Public Law No. 115-123, Section 53113 amends section 1860D-14A(g)(2)(A) of the Social Security Act so that it now defines applicable drugs to mean drugs that are 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 (PHSA) (other than with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351).