

Coverage Gap Discount Program Labeler Code Read Me File

Purpose of File: This file is provided for use by Part D sponsors, Manufacturers, Pharmacy Benefit Managers, and Pharmacies as part of the Centers for Medicare & Medicaid Services (CMS) Coverage Gap Discount Program (Discount Program). Since 2011, Medicare Part D only covers brand-name drugs or biologics from manufacturers that have signed agreements with Medicare to provide a 50% discount on their brand-name drugs or biologics for coverage gap claims. Public Law No. 115-123, also known as the Bipartisan Budget Act of 2018 (BBA) enacted on February 9, 2018 increased the manufacturer discount from 50% to 70 % effective 2019 for applicable drugs. Brand-name drugs and biologics associated with labeler codes in the file named *Participating Labeler Codes* will continue to be covered under Part D in 2019.

Description of File: The file provided is in MS Excel, CSV, and Text formats. The fields are defined as follows:

Manufacturer Name: The name of the manufacturer who signed a Discount Program agreement.

P Number: The unique number assigned to the manufacturer by CMS.

Labeler Codes: The first five digits in the 11-digit national drug code (NDC) format that is assigned to the manufacturer by the Food & Drug Administration (FDA). A labeler code may be listed even if the manufacturer does not currently have any FDA- approved or brand name drugs products on the market. If no labeler code is provided, the manufacturer has signed a Discount Program agreement but may not yet have a FDA- issued labeler code.

Labeler Code Firm Name: The firm name identified either on the FDA website or by the Manufacturer. Where the firm name differed between the FDA website and the manufacturer, CMS deferred to the FDA website listing.

Date Added: Represents the date that CMS publishes to the industry, and identifies the date that coverage for brand-name drugs under the labeler code are eligible for a discount in the coverage gap.

Effective Date: Represents the date the identified manufacturer became responsible for paying discounts for the eligible labeler code.