



Disabled and Elderly Health Programs Group

October 17, 2019

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 111

For

Participating Drug Manufacturers

Changes to Calculation of Average Manufacturer Price (AMP) under Medicaid Drug Rebate Program for Authorized Generics (as required under the Pub. L. 116-59, the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019)

On September 27, 2019 the President signed into law Pub. L. 116-59, the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, which made changes to section 1927(k)(1) of the Social Security Act (the Act), revising how manufacturers calculate the average manufacturer price (AMP) for a covered outpatient drug, for which the manufacturer permits an authorized generic to be sold. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall no longer include sales of these authorized generics in the calculation of AMP.

Specifically, section 1603 of Health Extenders Act, which is titled - *Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition Of Wholesaler*, amended:

- Section 1927(k)(1)(C) of the Act to replace the term "inclusion" with "exclusion" in the title and further amended subparagraph (C) to read - In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

An authorized generic is a product that a manufacturer (primary manufacturer) typically allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's FDA approved NDA but under a different NDC number. The authorized generic is typically a lower price form of the primary's manufacturer's brand product. Primary manufacturers that sell the authorized generic product to a secondary manufacturer refer to these sales as transfer sales. Under the amendments made to section 1927, a primary manufacturer that sells the authorized generic version of the brand drug to the secondary manufacturer cannot include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP.

Section 1603 is effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with 42 CFR § 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

Sincerely,

/s/

Alissa Mooney DeBoy
Acting Director
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