

Congress Amends Medicaid Drug Rebate Statute Treatment of Authorized Generic Drugs in AMP

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On the heels of an April 2019 audit report published by the Department of Health and Human Services, Office of Inspector General (HHS-OIG) finding that Medicaid could save hundreds of millions of dollars in Medicaid drug rebates, Congress has passed legislation that amends critical provisions of the Medicaid Drug Rebate Statute (42 U.S.C. § 1396r-8) related to the treatment of authorized generic drugs in the Average Manufacturer Price (AMP) calculation for branded drugs effective October 1, 2019.

Relevant Provisions of the Medicaid Drug Restate Statute

The Continuing Appropriations Act of 2020 and Health Extenders Act of 2019 (referred to in relevant part as Health Extenders Act of 2019), signed into law on September 27, amends the Medicaid Drug Rebate Statute in two keys ways: (1) it requires manufacturers to exclude (rather than include) the prices paid by wholesalers to manufacturers for authorized generic drugs in the AMP calculation for the branded drug and (2) it deletes references to “manufacturers” from the definition of wholesaler. The specific amendments to the text of the Medicaid Drug Rebate Statute are as follows:

~~Inclusion~~ **Exclusion** of section 505(c) drugs. In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold ~~under a new drug application the manufacturer's new drug application~~ approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be ~~inclusive~~ **exclusive** of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

42 U.S.C. § 1396r-8(k)(1)(C)

The term “wholesaler” means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) ~~manufacturers~~, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including ~~manufacturer's and~~ distributors warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

42 U.S.C. § 1396r-8(k)(11)

Recent Audit Report by HHS-OIG

In the April 2019 audit report, HHS-OIG “recommended that the Centers for Medicare & Medicaid Services (CMS) seek legislative change to exclude authorized generic drug transactions to secondary manufacturers from the AMP calculation of the brand name drug” CMS responded to HHS-OIG’s recommendation by stating that the agency concurred with this recommendation and the President’s fiscal year 2020 budget included such a legislative proposal.

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The amendments to the Medicaid Drug Rebate Statute under the Health Extenders Act of 2019 will surely have an impact on branded drugs with authorized generic versions. Stakeholders should expect that CMS will issue regulations, and potentially a Medicaid Drug Program Manufacturer Release in the interim, to implement these amendments.

For more on other breaking drug pricing related news, visit [Sidley's Global Drug Pricing](#) page.

CONTACTS

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