DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Medicaid and CHIP Services

May 18, 2020

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 112**

For Participating Drug Manufacturers

Further Recommendations on Calculation of Average Manufacturer Price (AMP) of Brand Name Drug and Authorized Generic Drugs (resulting from statutory changes in Continuing Appropriations Act, 2020, and Health Extenders Act of 2019)

On October 17, 2019, the Centers for Medicare & Medicaid Services (CMS) issued Manufacturer Release No. 111 detailing the changes made to the calculation of average manufacturer price (AMP) under the Medicaid Drug Rebate Program (MDRP) by the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Pub. L. 116-59). Specifically, in accordance with section 1603 of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019, section 1927(k)(1)(C) of the Social Security Act (the Act) was amended, replacing the term "Inclusion" with "Exclusion" in the subparagraph heading and further revising 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* (emphasis added). Section 1603 also amended the definition of wholesaler at 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

After the passage of the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 and issuance of Manufacturer Release No. 111, CMS received questions from the industry regarding manufacturer ownership arrangements and how the revisions to the calculation of AMP for the authorized generic and brand name drugs apply in certain fact-specific situations, including the situation in which the NDA holder markets both the brand drug and an authorized generic version of the brand drug, and the situation in which the NDA holder has an affiliation with another manufacturer to market the authorized generic version of the NDA holder's brand drug. We address these situations with this guidance.

Prior to the statutory change, CMS indicated that when a single manufacturer is selling two versions of a product under the same NDA, section 1927(k)(1)(C) of the Act provides that the AMP of the brand drug be inclusive of the authorized generic product sales when a manufacturer

sells the product to a wholesaler who distributes to the retail community pharmacies[1]. We advised that "In such cases the price of the drug would be blended for AMP even if the manufacturer may have given the drug a different product code." Now that the statute has been amended to require that the AMP calculation for such brand drug be determined excluding the average price of the authorized generic paid by wholesalers for drugs distributed to retail community pharmacies and manufacturers can no longer be considered wholesalers, manufacturers are required to modify their AMP calculations for the brand product to ensure such prices are excluded from the calculation of AMP for the brand drug. CMS plans to address the calculation of AMP for the brand drug and the authorized generic version in more detail through future rulemaking.

Until we issue a regulation in final, we are advising that when a manufacturer approves, allows, or otherwise permits any of its drugs to be sold under the same NDA, a separate AMP should be calculated for each drug product – that is, one AMP for the brand drug, and one AMP for the authorized generic product, and the AMP for the brand drug should exclude sales of the authorized generic product. We are advising that this includes both the situation when a manufacturer is the same for both the brand drug and authorized generic version and the situation when the drugs are being manufactured by different, but affiliated companies. For example, the manufacturer making the authorized generic might be a subsidiary of the brand name company, or the two might simply have a corporate or business relationship.

In addition, one single "best price" should continue to be reported for both the brand name drug and the authorized generic version. Best price is defined at section 1927(c)(1)(C)(i) to mean, with respect to a single source drug or innovator multiple source drug of a manufacturer (*including the lowest price available to any entity for any such drug of the a manufacturer that is sold under a new drug application approved under section 505(c) of the FFDCA*) (emphasis added), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States.

Moreover, the statutory definition of best price at section 1927(c)(1)(C)(ii)(IV) expressly provides that in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the FFDCA, best price shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to best price eligible entities. Therefore, the manufacturer's determination of best price shall be reflective of the lowest price available to any entity for any such drug sold under a manufacturer's NDA and also be inclusive of the lowest price for such authorized drug under 505(c), which means best price for both the brand product and the authorized generic would be the same, and be based on sales of both products.

[1] 81 FR 5260

We remind manufacturers that in the absence of specific guidance, the manufacturer may make reasonable assumptions in its calculation of AMP (monthly and quarterly) and best price, consistent with the general requirements and intent of section 1927 of the Act, applicable federal regulations and the Medicaid drug rebate agreement. See Manufacturer Release 78. As always, we request that manufacturers not submit their assumptions to CMS. Rather, a record (written or electronic) outlining these assumptions must be maintained by the manufacturer in accordance with the recordkeeping requirements in 42 CFR § 447.534. Should a manufacturer disregard these instructions and submit such assumptions, they will not be reviewed and their receipt should not be considered as acquiescence by CMS to the submitted assumptions.

Sincerely,

Alissa M. Deboy -S

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Director
Disabled and Elderly Health Programs Group