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Center for Medicaid and CHIP Services

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MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 117**

For

Participating Drug Manufacturers

Impact of Certain Changes on Average Manufacturer Price (AMP) and Medicaid "Best Price"

This program release addresses the impact of certain changes on pricing metrics for drug manufacturer covered outpatient drugs (COD) required to be reported under the Medicaid Drug Rebate Program (MDRP). Specifically, this release explains the impact on a manufacturer's average manufacturer price (AMP) and Medicaid "best price" from:

- Manufacturer Medicare Part B discarded drug refunds;
- Sales of CODs in the U.S. Territories; and,
- Inflation Reduction Act of 2022 (IRA) Medicare Part B and D inflation rebates and the establishment of a maximum fair price (MFP) for certain Part B and D drugs and biologicals.

These modifications result from several recent statutory and regulatory changes, which include changes resulting from the enactment of the IRA, the Infrastructure Investments and Jobs Act of 2021 (the Infrastructure Act), and the final regulation issued on November 19, 2021, CMS-2482-F2 (*Medicaid Program; Delay of Effective Date for Provision Relating To Manufacturer Reporting of Multiple Best Prices Connected to a Value-Based Purchasing Arrangement; Delay of Inclusion of Territories in Definition of States and United States)* relating to sales of manufacturers' drugs in the U.S. territories.

Impact of Medicare Discarded Drug Refunds on Average Manufacturer Price (AMP) and Best Price

Section 90004 of the Infrastructure Act amended section 1847A of the Social Security Act (the Act) to require manufacturers to provide a refund to the Centers for Medicare & Medicaid Services (CMS) for certain discarded amounts from a refundable single-dose container or single-use package drug furnished under the Medicare program, effective January 1, 2023.

Section 1847A(h) of the Act requires manufacturers to provide refunds for discarded amounts exceeding an applicable percentage, which is required to be at least 10 percent, of the estimated total allowed charges for such a drug (less the amount paid for packaged drugs) during the quarter. For more information on Medicare's final rule regarding the refund for discarded amounts and the applicable percentage, see Medicare Physician Fee Schedule final rule, specifically the section *Implementing Requirements for Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts*.

Section 1927(k)(1)(B)(i)(III) of the Act states that AMP shall exclude reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing. CMS implemented this statutory language in regulations for the determination of AMP (see 42 CFR §§ 447.504(c)(16) and (e)(7)), and the determination of best price (see 42 CFR § 447.505(c)(14)). Since Medicare Part B discarded drug refunds represent reimbursement by manufacturers to Medicare for a discarded amount that is "otherwise unsalable returned goods" manufacturers may exclude these discarded drug refunds from determinations of best price and AMP (including 5i AMP[1]).

Inclusion of Territories' Sales in Average Manufacturer Price (AMP) and Best Price

In the February 1, 2016 *Medicaid Program: Covered Outpatient Drugs* final rule with comment period (2016 COD final rule), CMS, among other things, amended the regulatory definitions of "States" and "United States" at 42 CFR § 447.502 to include the U.S. territories (American Samoa, Northern Mariana Islands, Guam, Puerto Rico, and the Virgin Islands), effective April 1, 2017[2]. In response to stakeholders' concerns, and as a result of subsequent discussions on preparedness, the potential for increased Medicaid drug prices in certain territories, and later, due to additional impacts of natural disasters in several of the territories, CMS issued two interim final rules[3] with comment period (IFC) to further delay the effective date of including the U.S. territories in the regulatory definitions of "States" and "United States" for purposes of the MDRP. In the most recent IFC, CMS finalized the inclusion date for the amended regulatory definitions of "States" and "United States" at 42 CFR §447.502[4].

As a result, beginning January 1, 2023, manufacturers are required to include all sales of CODs in territories in their AMP and best price calculations. In the preamble to the COD final rule, CMS addressed the comment that urged CMS not to require manufacturers to include sales to territories in these calculations. CMS responded to the comment by indicating that sections 1927(c)(1)(C) and 1927(k)(1)(A) of the Act define best price and AMP to reflect certain prices paid in the United States consistent with section 1101(a) of the Act, which defines United States

[1] Under the MDRP, a separate AMP must be calculated for inhalation, infusion, instilled, implanted, or injectable drugs, referred to as 5i drugs.

[2] 81 FR 5170 (Feb. 1, 2016)

[3] 81 FR 80003 (Nov. 15, 2016), 84 FR 64783 (Nov. 25, 2019)

[4] 86 FR 64819 (Nov. 19, 2021)

for purposes of these provisions to include the territories. Therefore, manufacturers are responsible for including sales in the territories in their rebate calculations. We further noted that manufacturers should treat prices paid by entities in the U.S. territories in the same manner in which they treat prices paid by entities located in one of the 50 states and District of Columbia in AMP and best price (see 81 FR at 5224; see also 81 FR 80004; 84 FR 64784).

In the most recent final rule (CMS-2482-F2), CMS reiterated the discussion in the preamble of the 2016 COD Final Rule to remind manufacturers that if a territory decides to opt-out of participation in the MDRP in accordance with either section 1902(j) of the Act or using a waiver authority under section 1115 of the Act to waive section 1902(a)(54), manufacturers are required to include eligible sales and associated discounts, rebates, and other financial transactions that take place in the U.S. territories in their calculations of AMP and best price once the revised definitions of "States" and "United States" take effect, regardless of whether the U.S. territories seek to waive participation in the MDRP (see 86 FR 64821). Therefore, manufacturers must include eligible sales in the territories in their calculations of AMP (including AMP for 5i drugs) and best price starting January 1, 2023.

Impact of the Inflation Reduction Act of 2022 on Average Manufacturer Price and Best Price

On August 16, 2022, President Biden signed into law the IRA, which amended the Act to set forth significant drug pricing reforms for the Medicare program. Three such reforms include those establishing a Part B inflation rebate, a Part D inflation rebate, and a program allowing the Medicare program to negotiate a maximum fair price (MFP) for certain single source drugs and biologicals with the highest spend in Part B or Part D. The IRA also included specific conforming amendments to certain Medicaid drug rebate requirements. Below is a brief summary of the Medicare drug pricing changes and the impact of these changes on AMP and best price:

- **Part B Inflation Rebate** - Section 11101 of the IRA amended section 1847A of the Act, adding subsection (i), setting forth the requirement that manufacturers pay quarterly rebates for certain single source drugs and biologicals with prices increasing faster than inflation. Section 1847A(i) requires that, no later than 6 months after the end of each calendar quarter beginning on or after January 1, 2023, the Secretary of the Department of Health and Human Services (the Secretary) shall report to each manufacturer information on the total number of units of the billing and payment code of the Part B rebatable drug, information on the amount (if any) of the excess average sales price (ASP) increase for such drug and calendar quarter, and the rebate amount owed for such Part B rebatable drug and calendar quarter. For each calendar quarter beginning on or after January 1, 2023, the manufacturer of the Part B rebatable drug shall, no later than 30 days after date of receipt of the Secretary's information, provide a quarterly rebate equal to the amount as specified in 1847A(i)(3) of the Act. The Act allows the Secretary to delay reporting the rebate information for the calendar quarters beginning in 2023 and 2024 until September 30, 2025.

  Impact on AMP and best price: Section 11101(c)(2) amends the *Special Rules* section for defining best price at 1927(c)(1)(C)(ii)(I) indicating that best price as defined shall not be inclusive of such Part B inflation rebates under section 1847A(i). Section 11101(c)(4) also amends section 1927(k)(1)(B)(i) by adding a new subclause (VII) to the exclusions to AMP,

to exclude the rebates paid by manufacturers under 1847A(i). Therefore, Part B inflation rebates are excluded from AMP and best price.

- **Part D Inflation Rebate** - Section 11102 of the IRA added section 1860D-14B of the Act, setting forth the requirement that manufacturers be subject to annual Part D inflation rebates. For each applicable period (defined at 1860D-14B(g)(7) as the 12-month period beginning October 1 of each year) beginning on October 1, 2022, manufacturers shall provide to the Secretary a rebate that is equal to the rebate amount specified in 1860D-14D(b) of the Act if the Part D rebatable drug's annual manufacturer price in an applicable period exceeds the drug's inflation adjusted payment amount. Section 1860D-14B(a)(1) requires that the Secretary report the rebate information to the manufacturer no later than 9 months after the end of each applicable period. Section 1860D-14B(a)(2) requires manufacturers to pay the rebate equal to the amount specified in 1860D-14B(b) and reported by the Secretary, no later than 30 days after the receipt of the rebate information. The Act provides for a transition period, which allows the Secretary to delay reporting the rebate information and rebate amount to manufacturers for the initial applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

  Impact on AMP and best price: Section 11102(b)(2) amends the *Special Rules* section in 1927(c)(1)(C)(ii)(I) of the Act, indicating that best price as defined shall not be inclusive of such Part D inflation rebates under section 1860D-14B. Section 11102(b)(4) also amends section 1927(k)(1)(B)(i) by adding a new subclause (VIII) to the exclusions to AMP to exclude the rebates paid by manufacturers under 1860D-14B. Therefore, Part D inflation rebates are excluded from both AMP and best price.

- **Maximum Fair Price** - Section 11001 amends Title XI of the Act to add Part E, which establishes a drug price negotiation program to lower prices for certain high spend single source drugs and biologicals. The Secretary will publish a list of selected drugs, enter into agreements with manufacturers of these selected drugs for a price applicability period, and negotiate maximum fair prices (MFPs) for such selected drugs. The manufacturer must provide access to the MFP for a selected drug to Medicare beneficiaries and entities that furnish or administer drugs to Medicare beneficiaries, as provided for in the law. The MFP is effective beginning in the initial price applicability year. The first initial price applicability year begins on January 1, 2026.

  Impact on AMP and best price: Section 11001(b)(2) amends the *Special Rules* around best price in section 1927(c)(1)(C)(ii) by adding a new subclause (V) to indicate that in the case of a rebate period and a COD that is a selected drug (as referred to in section 1192(c)) during such rebate period, the best price shall be inclusive of the MFP (as defined in section 1191(c)(3)) for such drug with respect to such period. Section 11001(b)(3) also amends section 1927(k)(1)(B)(i) of the Act by adding subclause (VI) to the exclusions to exclude from AMP any reduction in price paid during the rebate period to the manufacturer for a drug by reason of application of part E of Title XI. Therefore, beginning January 1, 2026, the MFP for a selected drug shall be included in best price and excluded from AMP. Thus, a manufacturer's rebates due for a COD will be based on the MFP for a drug if it is the drug's best price.

If you have further questions regarding the impact of IRA requirements or other legislative changes mentioned in this release on manufacturer pricing, please send your inquiries to the CMS Rx DRUG Policy email box at rxdrugpolicy@cms.hhs.gov.

Sincerely,

/s/

Alissa Mooney DeBoy
Director
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