

Disabled and Elderly Health Programs Group

May 17, 2019

MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 110

For

Participating Drug Manufacturers

The Centers for Medicare & Medicaid Services (CMS) is releasing this notice to provide guidance to manufacturers on three topics. First, we are providing guidance regarding the treatment of rebates provided to Medicare Advantage (MA) plans (including MA plans that offer prescription drug coverage (MA-PD plans)) for Medicare Part B utilization in the manufacturer's determination of best price, calculation of a drug's Average Manufacturer Price (AMP) for inhalation, infusion, instilled, implanted, or injectable (5i) drugs (5i AMP) and Average Sales Price (ASP). Second, we are providing guidance to manufacturers that wish to voluntarily terminate from the Medicaid Drug Rebate Program (MDRP) on the best approach to notifying CMS of their intent to terminate their National Drug Rebate Agreement (NDRA). Finally, we are providing manufacturers with guidance on the optional versus mandatory effective dates of the NDRA.

Treatment of Rebates Provided to Medicare Advantage (MA) plans (including MA-PD plans) for Medicare Part B Utilization

In order to ensure greater consistency in best price and average manufacturer price calculation methodologies across manufacturers, we are issuing guidance on how manufacturer rebates negotiated by Medicare Advantage (MA) plans (including MA-PD plans) for Medicare Part B drugs should be reflected in best price, 5i AMP and ASP.

Best Price: Section 1927(c)(1)(C) of the Social Security Act (the Act), defines best price to mean, "with respect to a single source or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States...", subject to certain exclusions, including "any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA-PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or

any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A.” See § 1927(c)(1)(C)(i)(VI) of the Act. We further codified this exclusion in regulation at 42 CFR § 447.505(c)(6) and provided at section 447.505(b) that except for those prices identified in paragraph (c) as being *excluded from best price*, best price for covered outpatient drugs includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price-eligible entities listed in section 447.505(a). Therefore, the regulation implementing the statutory best price exclusions is clear and to the extent a price is not specifically excluded from the best price calculation by statute or regulation, such prices and associated discounts or other price concessions provided shall be included. Since rebates for Part B drugs negotiated by MA plans are not specifically excluded from best price in either statute or regulation, manufacturers must include such rebates in the determination of best price.

5i AMP: Section 1927(k)(1)(B)(i)(IV) of the Act provides that the calculation of AMP for 5i drugs that are not generally dispensed through a retail community pharmacy *includes* payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health management organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy. Section 447.504 codifies the statutory definition of AMP, and at paragraph (d) provides specifically that except for those sales, nominal price sales, and associated discounts, rebates, payments and other financial transactions identified in paragraph (e), AMP for 5i shall include sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions to all the entities specified in paragraph (b) as well as those specified in paragraph (d). Sales to insurers (MA plans would fall under the definition of insurers) including rebates negotiated by MA plans for Part B drugs are not excluded by statute or regulation and shall be included in the AMP for 5i drug price calculation.

ASP: There are no provisions in Section 1847A of the Act or the implementing regulations at 42 CFR Part 414, Subpart J that support excluding rebates negotiated by MA or MA-PD plans for Part B drugs from the calculation of the manufacturer’s ASP.

In summary, rebates for Medicare Part B drugs that are provided to MA plans shall not be excluded from the calculation of the drug’s best price, 5i AMP or ASP.

Please contact RxDRUGPolicy@cms.hhs.gov if you have any questions.

Manufacturer Voluntary Termination Notice of the National Drug Rebate Agreement(s) (NDRA)

In order to ensure prompt receipt of a manufacturer’s notice of voluntary termination per section 1927(b)(4)(B)(ii) of the Social Security Act (the Act) and section VII(b) of the NDRA, manufacturers are strongly encouraged to email their termination notices to drugrebateagreement@cms.hhs.gov.

The referenced email resource box is checked multiple times daily by CMS’s Division of Pharmacy (DP) staff. Section VII(b) provides that termination by the manufacturer becomes

effective the later of the first day of the first rebate period beginning 60 days after the manufacturer gives written notice requesting termination, or CMS initiates termination via written notice to the manufacturer, and section VIII(b) provides that any notice required under the NDRA is permitted in writing or electronically. Thus, manufacturers may still mail or courier their termination notices in addition to emailing them. However, in order to ensure prompt receipt of voluntary termination notices, manufacturers are strongly encouraged to email a copy of the termination notice.

Manufacturers receive a copy of CMS's email termination notice to states, and the termination notice is added to the list of labelers on CMS's New/Reinstated and Terminated Labeler Information at <https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/new-and-terminated-labeler/index.html>. If the manufacturer does not receive either of these notices within a week of sending CMS voluntary termination notice, please contact CMS and resend the notice.

As a reminder, per section II(b) of the NDRA, manufacturers are required to report all covered outpatient drugs (CODs) under all of their labeler code(s) to CMS. Therefore, if a manufacturer voluntarily terminates an NDRA that has active CODs, they must request termination for all associated labeler codes. If the request for termination does not include all associated labeler codes, please provide a justification for such request.

National Drug Rebate Agreement (NDRA) Optional Effective Date (OED) and Mandatory Effective Date (MED)

As discussed in Medicaid Program Manufacturer Release # 46, the Balanced Budget Refinement Act of 1999 amended section 1927(a)(1) of the Act to give states the option of using a different rebate agreement effective date than the date that was required prior to the amendment. Specifically, the law permits that a rebate agreement may become effective as of the date on which the agreement is entered into (referred to as the optional effective date (OED)) or, at the State's option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the agreement is entered into (referred to as the mandatory effective date (MED)).

CMS has issued guidance regarding manufacturers' data reporting and rebate calculation requirements under an executed NDRA, including:

- Section II(b) of the NDRA, which states, “*(b) Beginning with the quarter in which the National Drug Rebate Agreement (rebate agreement) is signed for all covered outpatient drugs of all labeler codes of a manufacturer, calculate, and report all required pricing data on every covered outpatient drug by NDC in accordance with section 1927 of the Act and as implemented by [42 CFR 447.510](#).*”
- Manufacturer Release #46, which states, “*Please note that as a result of this legislation, labelers must submit baseline AND pricing data for the quarter in which your agreement is postmarked in case any States wish to cover your products using the optional effective date.*”

- The Medicaid Drug Rebate Data Guide for Labelers, section 2.2, states, “*Labelers are required to report initial product and pricing information on all covered outpatient drugs within 30 days of the end of the month and quarter of the optional effective date.*”

To clarify, the OED is the date on which the rebate agreement is executed and the date on which a state may begin to utilize a manufacturer’s CODs under the terms of the NDRA. The OED determines the date on which manufacturer reporting of its drug product and pricing information are first due and rebate liability begins. The MED is the latest date on which a state must meet its obligations under the MDRP for that manufacturer.

We note that issuance of an NDRA to a manufacturer before its first COD is marketed may reduce the time afforded the state by law during the OED period to review the drug and determine coverage policies before the MED. In this regard, some manufacturers have requested that CMS execute an NDRA well in advance of the planned marketing date of the manufacturer’s first COD.

As we advise on the Medicaid.gov website (<https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/national-drug-rebate-agreement/index.html>), drugs should be ready to market in the same quarter in which a rebate agreement is requested, if not already on the market. This is because under an executed NDRA, manufacturers are required to report certain pricing data to CMS in order for the agency to calculate Unit Rebate Amounts (URAs) used by the state to bill manufacturers for rebates, including the correct base date AMP. These pricing data are likely only able to be reported by the manufacturer if the drug is actually available for sale in the market.

CMS will review the manufacturer’s NDRA request and, if there are no outstanding issues, have it ready for prompt execution and state notification. This will allow states to cover the drug during the OED period when it becomes available if they choose to do so before the MED. We strongly encourage prospective manufacturers that have not yet marketed a COD to not request an NDRA until shortly before their first COD’s planned market date for the reasons stated above.

States should ensure that they have a process in place to review the CODs of new labelers during the OED period, and to inform their providers of any decision to start coverage of a manufacturer’s CODs by providing the labeler code, if desired, prior to the MED.

Please direct any questions on the above two items to drugrebateagreement@cms.hhs.gov.

Sincerely,

/s/Alissa DeBoy
Alissa DeBoy
Acting Director
Disabled and Elderly Health Programs Group