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

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 118**

For

Participating Drug Manufacturers

This program release clarifies system instructions regarding the reporting of reused National Drug Codes (NDCs) and the timing of reporting new NDCs in the Medicaid Drug Rebate (MDP) system. It also reminds manufacturers of our policy regarding warranty payment arrangements.

Reporting Reused NDCs

Historically, the Food and Drug Administration (FDA) permitted the reuse of an NDC if the product had been discontinued for at least five years. However, FDA regulations[1], effective November 29, 2016, prohibit the reuse of an NDC if the NDC was previously assigned to a different drug. FDA regulations state that they will not reassign a discontinued NDC to a different drug that is submitted to them for listing.

Consistent with the FDA regulation, the reporting of a reused NDC for purposes of the Medicaid Drug Rebate Program (MDRP) will no longer be accommodated in the MDP system, effective January 1, 2024. The Centers for Medicare & Medicaid Services (CMS) believes that this system change will lead to improved patient safety. In addition to being out of alignment with FDA regulations, a reused NDC can make it appear as if a patient was prescribed and dispensed a different drug, which may result in problems such as incorrect interpretation of a patient's drug history. It also may hinder checks for drug interactions or allergy alerts. Also, the MDP system cannot maintain data for different products with the same 9-digit NDC (i.e., labeler code and product code). When an NDC is reused, the entire product and pricing history of the earlier product must be deleted before the data for the new product can be reported.

Prior to CMS implementing this change, manufacturers should review all of their NDCs that are reported to the MDP system, including any that are already terminated, to ensure that the NDC represents the product most recently labeled with that NDC. If a manufacturer's review reveals that the NDC in the MDP system does not represent the most current product (e.g., it was a reused NDC for which the manufacturer did not request that CMS delete the prior history), the manufacturer should contact MDROperations@cms.hhs.gov to request assistance with any

[1] 21 CFR § 207.33(d)(2)

discrepancies. Manufacturers should also ensure that the appropriate departments within their organization are aware of this release.

This information supersedes information previously provided in Manufacturer Releases Nos. 51 and 73 from June 27, 2001, and April 25, 2006, respectively. Additionally, the MDP Data Guide, found within the MDP system, will be updated with this information in the next revision to the Guide.

If a manufacturer has questions or concerns about the FDA assignment of NDCs, they should contact FDA at eDRLS@fda.hhs.gov.

Timely Reporting of New NDCs

The timely reporting of new NDCs to the MDRP is essential for the efficient operation of the Medicaid drug benefit and helps ensure that new medications are timely made available to Medicaid beneficiaries. CMS urges manufacturers to report a new NDC in the MDP system as soon as the NDC is available for sale, which could be concurrent with the manufacturer reporting the new NDC to the drug compendia.

Both states and manufacturers benefit from manufacturers reporting new NDCs as soon as they are available. Making the state Medicaid agencies aware of new NDCs for covered outpatient drugs that are covered under the MDRP can allow states to expeditiously determine coverage for such NDCs. Once manufacturers report and certify new NDCs, they can be immediately viewed in the MDP system. Additionally, states and other interested parties can view this information in quarterly drug files and weekly additions to the quarterly files through the Medicaid.gov website. This can result in manufacturers seeing that their new drugs are covered by the state Medicaid programs more quickly.

Prompt reporting can also ensure compliance with laws and regulations. Section 1927(b)(3) of the Social Security Act, 42 CFR § 447.510, and the Medicaid National Drug Rebate Agreement all include requirements for manufacturers to report data on their covered outpatient drugs. These requirements presume that the NDCs for these drugs have been timely reported to CMS. Reporting a new NDC into the MDP system for the manufacturer helps ensure compliance with its other reporting responsibilities. For example, manufacturers are required to report monthly Average Manufacturer Price (AMP) not later than 30 days after the last day of each prior month. To comply with this requirement for a new NDC, the new NDC needs to be entered into the MDP system prior to this deadline.

Reiteration of CMS Position on Warranty Payment Arrangements

In response to requests from manufacturers regarding the use of warranty payment arrangements, we want to restate what was published in the December 31, 2020 final rule ***Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements***. This rule set forth requirements on manufacturer reporting as it relates to a manufacturer's value-based purchasing arrangements.

The following comment was published (in part) in the final rule (85 FR 87020):

> *Commenters also requested that ''warranty-type'' insurance models (this model obligates a premium payment by the manufacturer to a health plan to pay for a patient's future healthcare costs if the therapy fails) be outside of the proposed definition of VBP and that the revisions adding VBP arrangements to the proposed bundled sale definition and multiple best price calculations would not apply to such warranty models.*

In response, CMS indicated (in part):

> *We do not want to inadvertently narrow the definition of VBP arrangements by identifying specific models or structures and believe the definition of VBP arrangement in this final rule is sufficiently broad to potentially capture the various arrangements noted by the commenters when it would be appropriate.*

We went on to say that in the case of warranty arrangements (emphasis added):

> *The premium paid by the manufacturer to a third party to warrant a drug and provide benefits to payers and patients when certain clinical or performance measures are not achieved serves as an incentive to payers, providers, and patients to purchase the drug. Therefore,* ***the premium paid by a manufacturer reduces the drug's price and must be included in ''best price.''*** *However,* ***the benefits paid by the third party in the event the drug did not meet certain clinical or performance measures are exempt from ''best price'' because payments made from the third party to the payer do not represent a price available from the manufacturer to any best price eligible entity as provided in § 447.505(a) and does not represent a manufacturer sale to an AMP eligible entity consistent with § 447.504(b) or (d)****.*
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> *Therefore, under this warranty model, a manufacturer would pay both Section 1927 rebates for the drug, as well as pay for a premium for a warranty policy, the value of which they would have to be included in the calculation of their best price, regardless of whether the manufacturer uses a VBP arrangement that results in multiple best prices.*

Under a warranty payment arrangement described above, we believe manufacturers would not need to take advantage of the revised "multiple best price" approach for VBP arrangements in accordance with 42 CFR § 447.505(a), but rather the manufacturer would include its payment for the premium to the third party in the single best price. The outlay of any refund because of the warranty on the drug made by the third party would not be included in the single best price for the reasons stated above.

If you have further questions regarding the items in this release, please send your inquiries to the CMS Rx DRUG Policy email box at rxdrugpolicy@cms.hhs.gov.

Sincerely,

Alissa Mooney DeBoy
Director
Medicaid Benefits and Health Programs Group