DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

Medicaid Benefits and Health Programs Group

June 26, 2024

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 192**

For States

Information for States on Potential Unit Rebate Amount (URA) Changes for Prior Periods Due to Drug Classification Changes for Drugs Granted a Narrow Exception (NE) Under the Medicaid Drug Rebate Program

This release provides state guidance relevant to the information that was included in Manufacturer Release No. 120, dated June 26, 2024, pertaining to a change in the manufacturer's drug category reporting for drugs for rebate periods prior to April 1, 2016, where the Centers for Medicare & Medicaid Services (CMS) approves a narrow exception (NE) consistent with the Medicaid Program's Covered Outpatient Drug final rule with comment (CMS-2345-FC), 81 FR 5170 (Feb. 1, 2016) ("Final Rule").

This release provides states with guidance on state processes with regard to claiming Federal Financial Participation (FFP) for a drug rebate credit when the drug category change to noninnovator (N) is due to an NE approval regardless of the effective date of the change. While Manufacturer Release No. 120, which is included as Appendix A, addresses the changes that may occur prior to April 1, 2016, this State Release provides information to states that may wish to make an adjustment to reported expenditures for FFP purposes resulting from a drug category change.

As noted in Manufacturer Release No. 120, the manufacturer should contact the affected states to provide notification via the Prior Quarter Adjustment Statement (PQAS) within 90 days of CMS's notification to the manufacturer that the manufacturer's decision to change the drug category from single source drug (S) or innovator multiple source drug (I) to N for periods prior to the second quarter (2Q) 2016 has been implemented. The manufacturer's notification to the states should include details and an explanation of the suspected overpayment of drug rebates to the state (i.e., a CMS-approved drug category change resulting in a credit back to the manufacturer). As part of that notification to states, we also recommend that manufacturers include an initial proposal for the recovery of the suspected overpayment, and then work with each state to arrive at an agreed-upon overpayment recovery solution. For example, while some states may be willing to issue a refund in full to the manufacturer, other states may need the manufacturer to recover the overpayment as a series of smaller credits that are issued over a period of multiple quarters. Whichever overpayment recovery option is ultimately utilized, we

expect manufacturers and the states to work together to ensure the states are not unnecessarily burdened by large overpayment amounts.

Claiming an expenditure on the Form CMS-64 in light of a drug category change

To the extent that CMS permits a manufacturer to change the drug category of a National Drug Code (NDC) that may result in a prior period adjustment to the Unit Rebate Amount (URA), if the state wishes to make an adjustment to reported expenditures for FFP purposes, the state needs to modify the Form CMS-64 for relevant expenditures. The Form CMS-64 is the accounting statement that the state agency, in accordance with 42 CFR § 430.30(c), submits each quarter under Title XIX of the Social Security Act. States must reduce the drug rebates previously reported on the Form CMS-64 for each of the quarters in which the manufacturer requests a credit from the state. In order to receive FFP associated with such reductions in drug rebates, the state's claim for FFP must meet the statutory and regulatory requirement to file claims for FFP within two years of the last day of the quarter in which an expenditure is made. Therefore, a state must submit the prior period adjustment on the Form CMS-64 within two years of the last day of the quarter in which the initial expenditure for the drug was made; if the prior period adjustment is submitted more than two years after the last day of the quarter in which the original expenditure was made, the state must meet a statutory or regulatory exception to the two-year time limit to receive FFP. Therefore, to meet the good cause waiver exception, the circumstances causing the late claim must meet statutory and regulatory requirements, the state must request a good cause waiver with the appropriate NDCs and quarters specified in the request, and the state must receive approval for such a waiver from CMS. Per 45 CFR 95.22, one example of a circumstance beyond the state's control includes documented action by the Federal Government.

With respect to the NE process, if the NE is approved, manufacturers may change the drug category of an NDC to N if it was previously reported as an S or an I. The effective date of such changes may vary depending on specific facts and circumstances. As explained in Manufacturer Release No.120, the effective date may depend on whether CMS grants those drugs that were first reported prior to April 1, 2016, the right to change the drug category prior to April 1, 2016. If any of these approvals result in a change to an NDC that was reported to CMS more than two years ago, and a state first reported collected rebates on the Form CMS-64 more than two years ago, the state will not be able to submit an adjustment to the Form CMS-64 without requesting a good cause waiver in writing, and CMS approval of such a waiver. States should make such a request as soon as the state recognizes that it will be unable to submit a claim within the appropriate time limit as specified in 45 CFR 95.25. The state must provide documentation of the circumstances beyond the state's control (e.g., issuance of Manufacturer Release No. 120) to justify the granting of a good cause waiver as specified in 45 CFR 95.28.

If you have any questions about seeking a good cause waiver or the timelines for FFP, please email Stuart Goldstein at Stuart.Goldstein@cms.hhs.gov.

Sincerely,

/s/

Alissa Deboy
Director
Medicaid Benefits and Health Programs Group

Appendix A

Copy of manufacturer release 120

DEPARTMENT OF HEALTH & HUMAN SERVICES
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Medicaid Benefits and Health Programs Group

June 26, 2024

MEDICAID DRUG REBATE PROGRAM NOTICE **Release No. 120**

For

Participating Drug Manufacturers

DRUG CLASSIFICATION FOR DRUGS GRANTED A NARROW EXCEPTION

In this Manufacturer Release, the Centers for Medicare & Medicaid Services (CMS) is informing manufacturers of the agency's decision related to timely submitted requests for a Narrow Exception (NE) and approved reporting of a National Drug Code (NDC) as a noninnovator multiple source drug (N) drug for periods prior to April 1, 2016.

In the Medicaid Program's Covered Outpatient Drug final rule with comment (CMS-2345-FC), 81 FR 5170 (Feb. 1, 2016) ("Final Rule"), and subsequent Manufacturer Release No. 98 and Manufacturer Release No. 113, CMS indicated that certain drugs approved under a new drug application (NDA) might be more appropriately treated as if they were approved under an abbreviated new drug application (ANDA) and classified as N. Such drugs would thereby qualify for an NE to the rule that drugs marketed under an NDA (including section 505(b)(2) NDAs) should be classified as either single source (S) or innovator multiple source drugs (I). This NE would allow these drugs to be classified as N. In the Final Rule, CMS established the NE process by which manufacturers could submit a request to have CMS allow individual drugs approved under an NDA to be reported as N drugs.

CMS has been reviewing NE requests from manufacturers and providing responses approving or denying the NE requests. NE decisions are effective as of April 1, 2016, the effective date of the Final Rule. In many cases, CMS's responses also provided information regarding the manufacturers' obligations to correctly report the classification of the drug for its entire history in the Medicaid Drug Rebate Program (MDRP).

In response to CMS instructions to correct such a drug's classification for the entire history of a drug, some manufacturers expressed concerns regarding the drug classification for periods prior to April 1, 2016. In this Manufacturer Release, CMS is informing manufacturers of the agency's decision that if CMS approves a timely submitted request for an NE, we agree to allow the manufacturer to report the NDC specified in CMS's approval as an N drug for periods prior to April 1, 2016. Therefore, solely with respect to drugs that have already been granted an NE:

- A drug reported as N prior to the second quarter (2Q) 2016 can remain N pre-Final Rule (i.e., before April 1, 2016). No further action is required from manufacturers for such drugs.
- Manufacturers reporting a drug as S or I prior to 2Q2016 have the *option* to request that the drug be classified as N prior to 2Q2016. However, we note that the work and costs involved to operationalize such a change in all states and reconcile changes that go back a significant number of rebate quarters may outweigh the fiscal benefit to the manufacturers of recouping the difference in the rebate payments from the state Medicaid programs. CMS will require affected manufacturers to meet with CMS for discussion if the manufacturer wants to make such a change. Manufacturers must contact CMS in writing via RxDrugPolicy@cms.hhs.gov within 30 calendar days of the date of this Manufacturer Release to (1) inform us of their intention to change from S or I to N for periods prior to 2Q2016 and (2) to request a meeting regarding such a potential change. After meeting with CMS, the manufacturer will have 30 calendar days to inform CMS of the manufacturer's final decision to change from S or I to N. If CMS does not receive any written request from a manufacturer within 30 calendar days of the date of this Manufacturer Release, then the drug classification for periods prior to 2Q2016 will remain as is.

The same provisions described above shall apply if CMS grants an NE request in the future, modified so that the initial 30-calendar-day period begins to run on the date CMS grants the NE request. For example, if an NE request is initially denied and the manufacturer timely provides additional information within the parameters given in the initial denial letter, and CMS subsequently grants the NE request, then the same provisions described above shall apply. In addition, the information in this Manufacturer Release does not apply to any NDCs beyond those that are specifically granted an NE. If an NE request is denied, and if that drug is currently reported as N, it will need to be reported as S or I for the entire history of the NDC in the MDRP.

We have decided to allow manufacturers whose NE request has been approved to report the drug status as N throughout the history of the drug based on an agency's inherent authority to reevaluate its approach. After reviewing submitted NE requests and the supporting information submitted by manufacturers during the NE review process, and considering the operational effort for CMS, states, and manufacturers to implement pre-Final Rule changes in classification, CMS has made this decision for these limited circumstances given that the operational costs of implementing such changes may outweigh the fiscal benefits to the manufacturers of receiving refunds on rebates already paid. We recognize that the relief granted by this decision is consistent with the relief ordered in *STI Pharma, LLC v. Azar*, 613 F. Supp. 3d 152 (D.D.C. 2020), a decision that CMS did not appeal. CMS continues to believe that *STI Pharma* was wrongly decided. However, to avoid the burden, expense, and uncertainty associated with

continued litigation over the classification of drugs for which an NE has been granted by CMS, CMS will grant relief consistent with that ordered in *STI Pharma*.[1]

This Manufacturer Release only applies to drug classification reporting for periods prior to April 1, 2016, for a drug that is the subject of an NE request that is submitted to CMS timely as specified in Manufacturer Release No. 98 and approved for an NE. This Manufacturer Release does not apply to any other decisions regarding misclassification, pre-Final Rule changes outside of these limited circumstances, or other decisions regarding the classification of drugs for the MDRP.

Working with CMS to report the Drug Classification as N:

If a manufacturer ultimately chooses to request a drug classification change for an NDC that was granted an NE and report it as N in the MDRP system prior to 2Q2016, the manufacturer must complete the Product Data Template found at: Medicaid Drug Rebate Program Change Request | Medicaid. Because the NDC will be classified as N, the manufacturer will need to provide the BBA'15 Base AMP (i.e., the baseline Average Manufacturer Price (AMP) for N drugs established by the implementation of Section 602 of the Bipartisan Budget Act (BBA) of 2015 as described in Manufacturer Release No. 106. For those NDCs with a market date on or before April 1, 2013, the BBA '15 Base AMP quarter is equal to 3Q2014. If the market date of a NDC is after April 1, 2013, the BBA '15 Base AMP quarter is equal to the fifth full quarter after the quarter in which the market date falls. The template should be returned to CMS by the manufacturer within 30 calendar days of the manufacturer informing CMS of the manufacturer's decision in writing.

The manufacturer should contact the affected states to provide notification via the Prior Quarter Adjustment Statement (PQAS) within 90 days of CMS's notification to the manufacturer that the manufacturer's decision to change the drug category from S or I to N for periods prior to 2Q2016 has been implemented. The manufacturer's notification to the states should include details and an explanation of the suspected overpayment of drug rebates to the state (i.e., a CMS-approved drug category change resulting in a credit back to the manufacturer). As part of that notification to states, we also recommend that manufacturers include an initial proposal for the recovery of the suspected overpayment, and then work with each state to arrive at an agreed-upon overpayment recovery solution. For example, while some states may be willing to issue a refund in full to the manufacturer, other states may need the manufacturer to recover the overpayment as a series of smaller credits that are issued over a period of multiple quarters. Whichever overpayment recovery option is ultimately utilized, we expect manufacturers and the states to work together to ensure the states are not unnecessarily burdened by large overpayment amounts.

[1] CMS's decision to grant relief consistent with that ordered in *STI Pharma* is not an indication that any adverse decision or ruling, whether by the U.S. Court of Appeals for the District of Columbia Circuit or by the U.S. District Court for the District of Columbia, on a Medicaid issue automatically necessitates a change in Medicaid policy. *See generally United States v. Mendoza*, 464 U.S. 154, 154 (1984) (holding that the United States may not be barred from litigating an issue that was adjudicated against it in an earlier lawsuit brought by a different party).

If you have any questions or concerns regarding this release, please contact CMS at RxDrugPolicy@cms.hhs.gov.

Sincerely,

/s/

Alissa Deboy
Director
Medicaid Benefits and Health Programs Group