



Disabled and Elderly Health Programs Group

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MEDICAID DRUG REBATE PROGRAM NOTICE

Release No. 113

For
Participating Drug Manufacturers

Compliance with drug pricing and drug product information under the Medicaid Services Investment and Accountability Act of 2019

On April 18, 2019, the President signed into law the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116-16). Section 6 of the Medicaid Services Investment and Accountability Act of 2019 amended sections 1903 and 1927 of the Social Security Act (the Act) to grant the Secretary additional penalty and compliance authorities needed to address the misclassification and misreporting of drug pricing and drug product information by drug manufacturers for purposes of the Medicaid Drug Rebate Program (MDRP).

This program notice provides guidance for how CMS will be implementing the Medicaid Services Investment and Accountability Act of 2019 and explains how drug manufacturers can ensure they are complying with the drug pricing and drug product information reporting requirements in Section 1927 of the Act.

I. BACKGROUND

Congress created the MDRP as part of the Omnibus Budget Reconciliation Act of 1990. Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143 (codified as amended at 42 U.S.C. § 1396r-8). Under this program, as a condition of Medicaid payment for covered outpatient drugs, drug manufacturers must enter into agreements with the Secretary to rebate to states a portion of those payments. The amount of the rebate is determined by a formula set forth in section 1927(c) of the Act. 42 U.S.C. § 1396r-8(c). Generally, the formula to calculate the rebate that applies to a particular drug depends on whether the drug is classified as (1) a single source or innovator multiple source drug or (2) a noninnovator multiple source drug, with the former drug categories paying a greater percentage in rebates. Drug manufacturers that participate in the MDRP are required to report and certify certain drug pricing and drug product information about each of their drugs, including the drug's classification, to the Centers for Medicare & Medicaid Services (CMS).

Prior to the Medicaid Services Investment and Accountability Act of 2019, section 1927(k)(7)(a)(iv) of the Act defined a single source drug (S drug) as “a covered outpatient drug which is produced or distributed under an **original** new drug application” 42 U.S.C. § 1396r-8(k)(7)(a)(iv) (2018) (emphasis added). Similarly, the statute defined an innovator multiple source drug (I drug) as “a multiple source drug that was originally marketed under an original new drug application.”¹ And it defined a noninnovator multiple source drug (N drug) as “a multiple source drug that is not an innovator multiple source drug.”

Generally, a drug was classified as an S or I drug based on whether it was produced, distributed, or marketed under an “original new drug application” (original NDA). However, the law does not define the phrase “original NDA.” CMS’s longstanding interpretation of the term was that an original NDA is an NDA approved under section 505 of the Federal Food, Drug, and Cosmetics Act (FFDCA) (Pub. L. 75-717), as distinguished from one approved under an abbreviated NDA (ANDA) under section 505(j) of the FFDCA. In the 2016 Medicaid Program; Covered Outpatient Drug final rule with comment period (final rule) CMS codified this interpretation in the regulatory definitions of S and I drug, and added a narrow exception to that general rule for “very limited circumstances where . . . certain drugs [approved under an NDA] might be more appropriately treated as if they were approved under an ANDA and classified as a noninnovator multiple source drug.” 81 Fed. Reg. 5170, 5191 (Feb. 1, 2016). On May 2, 2016 CMS issued [Manufacturer Release No. 98](#) which provides guidance to manufacturers regarding how they may submit a request for a narrow exception.

In the final rule, CMS established a process by which manufacturers could submit narrow exception requests to have CMS treat individual drugs approved under an NDA as N drugs, and permit the manufacturers to report those drugs as such, prospectively from April 1, 2016, the effective date of the final rule. The final rule did not, however, excuse manufacturers from their obligation to correctly report drugs approved under an NDA as either S or I drugs prior to the effective date of the 2016 final rule. Notwithstanding CMS’s articulation of its interpretation of the statutory language and its admonition that the narrow exception policy is prospective only, several manufacturers have expressed disagreement with CMS’s interpretation prior to the final rule. Many of those manufacturers have misreported drugs marketed under an NDA as N drugs for periods prior to 2016 and have failed to correct the reporting.

To resolve this inconsistent application of our statute and regulation by manufacturers and to better enable CMS to enforce the statutory drug category definitions, Congress amended sections 1927 (42 U.S.C. § 1396r-8) and 1903 (42 U.S.C. § 1396b(i)(10)) of the Act through the Medicaid Services Investment and Accountability Act of 2019, to clarify the definitions for single source drug and innovator multiple source drug and to provide the Secretary with additional penalty and compliance authorities with respect to manufacturers that have misclassified a drug product or misreported drug pricing or drug product information for their drugs to the MDRP. Section 6 of the Medicaid Services Investment and Accountability Act of 2019 is titled “Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program.” Specifically, in

¹ The statute defined a multiple source drug as “a covered outpatient drug . . . for which there [is] at least 1 other drug product which . . . is rated as therapeutically equivalent . . . , is pharmaceutically equivalent and bioequivalent, . . . and . . . is sold or marketed in the United States during the period.” 42 U.S.C. § 1396r-8(k)(7)(A)(i).

subsection 6(c), subtitled “Clarifying Definitions,” Congress removed the words “original” and “originally” from the definitions of single source drug and innovator multiple source drug and added CMS’s narrow exception language. The definition for an S drug now reads as follows: “a covered outpatient drug . . . which is produced or distributed under a new drug application approved by the Food and Drug Administration . . . unless the Secretary determines that a narrow exception applies” 42 U.S.C. § 1396r-8(k)(7)(A)(iv) (2019). Similarly, the statute now defines an I drug as “a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration, unless the Secretary determines that a narrow exception applies. . . .” 42 U.S.C. § 1396r-8 (k)(7)(A)(ii)(2019).

The Medicaid Services Investment and Accountability Act of 2019 also gives the Secretary new enforcement authority to ensure drug manufacturers report the correct drug category and other drug product information and to impose penalties against manufacturers that knowingly misclassify or otherwise misreport their drug products. Specifically, expanded authority under section 1927(b)(3)(C)(ii) of the Act subjects a manufacturer to civil monetary penalties for reporting of false information including information related to drug pricing, drug product information, and data related to such information. Section 1927(b)(3)(C)(iii) of the Act established a new authority to issue civil monetary penalties against a manufacturer that knowingly misclassifies a drug. Additionally, newly-created section 1927(c)(4)(A) of the Act codifies manufacturers’ obligation to pay unpaid rebate amounts due to misclassification of covered outpatient drugs.² Also, under section 1927(c)(4)(B) of the Act, if a manufacturer fails to correct the misclassification of a drug in a timely manner, the Secretary can take any or all of the following actions: (1) Correct the misclassification on behalf of the manufacturer; (2) Suspend the misclassified drug and the drug’s status as a covered outpatient drug under the manufacturer’s rebate agreement, and exclude the misclassified drug from Federal financial participation (FFP) (correlating amendments to section 1903 of the Act); and (3) Impose civil monetary penalties for each rebate period during which the drug is misclassified subject to certain limitations. Section 1927(c)(4)(D) of the Act expressly provides that the imposition of such penalties may be in addition to other remedies available and does not exempt the manufacturer from or preclude the Secretary from pursuing other remedies and penalties.

II. SCENARIOS IN WHICH A GIVEN NDC MAY BE POTENTIALLY MISCLASSIFIED OR MISREPORTED:

Manufacturers should ensure that all of their covered outpatient drugs are correctly classified and reported in the Drug Data Reporting system (DDR) for the history of the NDC, including such NDCs that may no longer be active (i.e., the expiration date of the last lot of the NDC has been reached). Below, we describe some scenarios that may have led to an NDC being misclassified or misreported, in the past or currently.

² Section II.(f) of the National Drug Rebate Agreement also obligates a manufacturer to timely pay unpaid rebate amounts. That subsection provides as follows: “To the extent that changes in product, pricing, or related data cause increases to previously-submitted total rebate amounts, the manufacturer will be responsible for timely payment of those increases in the same 30-day time frame as the current rebate invoice.”

1. The NDC is part of the narrow exceptions process

CMS has a pending request for a narrow exception: CMS is continuing to review all requests for a narrow exception that have been submitted according to the guidance provided in [Manufacturer Release No. 98](#). CMS is committed to reviewing and adjudicating these requests as quickly as possible. The narrow exception was initially promulgated in the final rule and is effective prospectively beginning April 1, 2016. The disposition of a narrow exception request does not apply prior to the effective date of the final rule.

CMS grants a manufacturer's request for a narrow exception: If CMS grants a request for a narrow exception, the NDC should be classified as an N drug beginning with second quarter 2016, that is, the effective date of the final rule. Prior to the second quarter of 2016, the NDC should be classified as either an S drug or I drug, as applicable. If the NDC is not already classified as either an S or I drug, as appropriate, for those prior periods, the manufacturer should take the steps outlined below to correct the misclassification.

CMS denies a request for a narrow exception: If CMS denies a request for a narrow exception, the NDC should be classified as an S or I drug, as applicable, for the entire history of the NDC's status as a covered outpatient drug in the MDRP. If it is not, the manufacturer should take the steps outlined below to correct the misclassification.

2. Working with CMS to correct drug category

Many manufacturers that have reported incorrect drug category information have been contacted by CMS and some are currently working with us to correct their data, however, some manufacturers have not responded to our multiple communications. Any manufacturer that has currently or previously misclassified an NDC should contact rxdrugpolicy@cms.hhs.gov to provide the status of any ongoing communications with CMS regarding the correction of their data. In the event that a manufacturer has currently or previously misclassified an NDC but was not contacted by CMS, or has not requested a correction, that manufacturer should contact CMS at rxdrugpolicy@cms.hhs.gov to request a correction. Manufacturers should contact CMS within 30 days of the date of this guidance. A misclassified NDC for purposes of this guidance is any NDC produced or marketed under an NDA or licensed under a BLA that is currently or was previously reported to the DDR for Medicaid as an N drug.

Manufacturers that have a pending narrow exception request, with confirmation from CMS that it has received the request, do not need to contact us with regards to this guidance for those NDCs included on the request. Additionally, manufacturers that have been granted a narrow exception, have submitted all required change request templates, and the changes have been implemented and certified in DDR do not need to contact us with regards to this guidance for those NDCs.

The Medicaid Services Investment and Accountability Act of 2019 grants CMS the authority to correct the misclassification of a drug if the manufacturer has received notice and failed to take steps to correct the classification. CMS can and will do so for all appropriate quarters.

3. There are Issues Relating to Manufacturers' Drug Category Changes made in DDR

In addition to the scenarios above, there are instances when a manufacturer may have changed the drug category in DDR from N to S or I without submitting a request to CMS. This likely occurred during two time periods, which correspond to either the addition of the COD status field to DDR or the effective date of the Final Rule. Those drug category changes became effective in the DDR system in either 3Q2014 or 2Q2016 and have been used to calculate Unit Rebate Amounts prospectively from that effective date. (Additionally, the system remains open to manufacturers to change from N to either S or I.) In these cases, when a manufacturer changed a drug category in DDR from N to S or I without CMS intervention, an NDC may now be correctly classified as S or I, however, it may have been incorrectly classified as N in prior periods and the drug category may currently be incorrect in DDR for prior periods.

In such cases the manufacturer likely needs to submit a request to change the drug category going back to the market date or purchased product date (PPD) of the drug, whichever is later. As discussed above, the drug category for an NDC should be S or I for the history of the NDC if it was always produced, distributed, or marketed under an NDA, unless CMS has determined that a narrow exception applies. If a narrow exception applies, the drug category for that NDC should historically be reported as S or I, and can be changed to N, effective April 1, 2016. We use the FDA "applications.txt" file to verify the type of application associated with an application number. The file may be accessed using the link to the drugs@fda download file found on this FDA webpage: <https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files>.

4. The Labeler is currently reporting an NDC to the DDR with an incorrect Covered Outpatient Drug (COD) status

In December 2018, CMS implemented a validation process that compares several data fields that a manufacturer enters into the DDR to information found in several FDA data sources. Prior to the implementation of this process, DDR did not prevent a manufacturer from entering certain mismatched information. For example, an NDC may have been entered into DDR with COD status "01" which represents an abbreviated new drug application (ANDA) along with an FDA application number reflecting an NDA approval, not an ANDA approval. In this example, a manufacturer may have reported a drug category of N and DDR would have accepted this information. The validation process is intended to prevent this type of misreporting, however a number of NDA-approved NDCs remain in DDR with COD status "01" and drug category N because the validation process did not apply retroactively and manufacturers have not taken the appropriate steps to correct the data field. The only situation in which a drug that is produced or marketed under an NDA may be reported as an N drug is if a narrow exception was granted by CMS pursuant to the process established in the final rule. Any manufacturer that is reporting an incorrect COD status should contact rxdrugpolicy@cms.hhs.gov to request correction to the COD status and, if required, correction to the drug category.

III. MANUFACTURERS' CORRECTION OF PRODUCT DATA

If a manufacturer incorrectly reported a drug category of noninnovator “N” for any time period during which the appropriate drug category was single source “S” or innovator “I”, it should contact rxdrugpolicy@cms.hhs.gov and request that CMS correct the drug category in DDR.

As manufacturers evaluate their NDCs for compliance, they should also ensure they are accurately reporting the drug’s market date. As stated in section 4.15 of the Medicaid Drug Rebate Data Guide for Labelers *June 2019* (available within DDR), the market date for S, I, and N drugs marketed under an FDA-approved application (e.g., BLA, NDA, ANDA) is the earliest date the drug was first marketed under the application number by any labeler. If a drug was purchased or otherwise acquired from another labeler, the market date should equal the market date of the original product. However, if a market date entered into DDR falls on a date that is earlier than 9/30/1990, DDR automatically populates the market date field with a value of 9/30/1990 (because dates earlier than the start of the MDRP are not applicable).

In addition to being a required product data field under the MDRP, the market date is also used to determine the quarter that is used to establish each drug’s Baseline Average Manufacturer Price (AMP). Because the Baseline AMP is used to calculate the additional rebate portion of the Unit Rebate Amount (URA) calculation, accurate market date reporting is imperative in order to ensure that correct Baseline AMP values are established. Prior to the implementation of the additional rebate for N drugs, manufacturers may have reported a market date that represented the date they began marketing the drug, rather than the earliest date that the drug was marketed under the application number by any labeler. If this is the case, a manufacturer must request a change from the incorrectly reported market date to the correct one to ensure that the correct Baseline AMP is accurately reflected in DDR. CMS addresses a manufacturer’s responsibility with respect to correct reporting of baseline data for a drug that was purchased from another manufacturer in [Manufacturer Release No. 90](#) and [Manufacturer Release No. 101](#).

Generally, a manufacturer cannot make the aforementioned product data corrections in DDR without CMS intervention. In order to request corrections, a manufacturer should email rxdrugpolicy@cms.hhs.gov with a request for corrections to be made. The request should identify which data fields require correction. CMS will provide the manufacturer with the necessary templates needed to be completed and returned. If CMS identifies a misclassified NDC and notifies the manufacturer, we will generally include the necessary template as part of that notification.

For most product data changes, CMS will make the changes on behalf of the manufacturer in DDR, and those changes will subsequently be available for labeler certification. However, in some situations where quarterly and/or monthly pricing data must be updated as a result of the product data change, CMS will notify the manufacturer that certain pricing data fields have been “unlocked” in DDR to allow the manufacturer to enter required information. Regardless of whether CMS makes a data change on behalf of a manufacturer or whether the manufacturer enters required data directly in DDR, manufacturers will be required to certify the information as stated in 42 CFR §447.510. Until certification is complete, the changes in DDR are not final and will not be used in any quarterly rebate calculations or transmitted to the states as part of the

quarterly rebate files. Further, newly reported monthly and quarterly pricing data that is not certified prior to the end of the applicable reporting period in which it's due will be considered late and those fields will display as missing pricing data on the manufacturer's Labeler Status screen in DDR. Until any product data changes and pricing data changes are certified, the previously certified values will remain in effect; therefore, until the manufacturer certifies the product data changes and the pricing data changes, the drug's product data and pricing data, including misclassified drug categories and misreported drug-pricing data, *will continue to be considered misclassified or misreported.*

If a manufacturer does not certify the corrected information, not only will the NDC be out of compliance, but additionally, as discussed above, the Medicaid Services Investment and Accountability Act of 2019 gives the Secretary new and expanded enforcement authority to ensure drug manufacturers report the correct drug category and drug product data.

In addition to penalties previously discussed, manufacturers could be subject to other possible compliance action or penalties, including, but not limited to, referral to the Health and Human Services Office of the Inspector General and/or the U.S. Department of Justice.

Sincerely,

/s/

Alissa Mooney DeBoy
Director
Disabled and Elderly Health Programs Group