U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

REPORT TO CONGRESS

Medicaid Services Investment and Accountability Act of 2019 Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program
Federal Fiscal Year 2024

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Executive Summary

This report to Congress fulfills the requirement of section 1927(c)(4)(C) of the Social Security Act (the Act), as added by section 6 of the Medicaid Services Investment and Accountability Act of 2019 (MSIAA) (P.L. 116-16). MSIAA requires the Secretary of the Department of Health and Human Services (HHS) to submit a report to Congress on an annual basis that includes information on the covered outpatient drugs (CODs) (as defined in section 1927(k)(2) of the Act) that have been identified as misclassified in the Medicaid Drug Rebate Program (MDRP), any steps taken by the Centers for Medicare & Medicaid Services (CMS) to reclassify such drugs, the actions the Secretary of HHS has taken to ensure the payment of any drug manufacturer rebate amounts which were unpaid as a result of such misclassification, and a disclosure of expenditures from the fund created in section 1927(b)(3)(C)(iv), including an accounting of how such funds have been allocated and spent in accordance with such subsection. This report contains information on activities performed to date and those planned to implement MSIAA to address drug misclassification as well as other action CMS has taken to improve oversight over the MDRP to ensure drug manufacturers' compliance with reporting requirements under section 1927.

Under the MDRP, states provide coverage of prescribed drugs and receive Federal Financial Participation (FFP) for those drugs, as long as the coverage complies with certain Federal requirements. Manufacturers seeking Medicaid coverage of their CODs must enter into a National Drug Rebate Agreement (NDRA) with the Secretary of HHS and comply with the law and the requirements of the NDRA. The requirements include manufacturer reporting of specified product and pricing data for their CODs to CMS on a monthly and quarterly basis. These data are used to calculate the amount of rebates that manufacturers must provide to the states for drugs that are paid for by the state in a calendar quarter; states, in turn, share those rebates with the Federal government through a reduction in Federal Medical Assistance Percentages (FMAP) or FFP. Misreported pricing and product data by a manufacturer may lead to inaccurate calculation of the manufacturer's rebate liability.

CMS endeavors to ensure accurate reporting of the data and has been actively addressing issues relating to manufacturers' compliance with their statutory reporting obligations. Such activities have included enhanced oversight by CMS of the information submitted by manufacturers through improvements in the reporting system, new regulations that have provided additional agency oversight capabilities, and more aggressive review of the data reported by manufacturers to CMS.

MSIAA added several tools to assist in CMS's oversight of the MDRP, which CMS codified in final regulations effective November 19, 2024.[1] CMS will use these new tools in continued enforcement of manufacturer reporting requirements.

[1] https://www.federalregister.gov/documents/2024/09/26/2024-21254/medicaid-program-misclassification-of-drugs-program-administration-and-program-integrity-updates

Background

Under the Medicaid program, section 1905(a)(12) of the Act gives states the option to provide coverage of prescribed drugs and to date, all states have elected to do so. Once a state elects to cover prescribed drugs, those prescribed drugs that meet the definition of a COD, as defined in section 1927(k) of the Act, must comply with the requirements of section 1927 of the Act (see section 1902(a)(54)). Section 1927 governs the MDRP and payment for CODs. Section 1903(a) governs the FMAP that states may receive when paying for CODs.

In general, for payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into an NDRA as set forth in section 1927(a) of the Act. (See also section 1903(i)(10) of the Act conditioning FFP in medical assistance for drugs covered under section 1902(a)(54) of the Act on the manufacturer of the drug having an NDRA). The rebates paid by manufacturers to states help to partially offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries.

The amount of the rebate is determined by a formula set forth in section 1927(c) of the Act. 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 drug or innovator multiple source drug, commonly referred to as a brand-name drug, or (2) other drugs, which include noninnovator multiple source drugs, commonly referred to as generic drugs. Generally, pursuant to section 1927 of the Act, drugs classified as single source drugs or innovator multiple source drugs pay higher rebates than those that are classified as an "other drug," such as noninnovator multiple source drugs.

While CMS provides unit rebate amounts (URAs) to the states each quarter as a courtesy to help facilitate billing manufacturers for rebates, it is ultimately the manufacturer's responsibility to calculate URAs and provide timely payment of rebate amounts to states for their CODs. In order for CMS to be able to calculate the rebate information to provide to the states, manufacturers must report certain drug product and pricing information to CMS in accordance with the Act. Specifically, consistent with section 1927(b)(3)(A) of the Act and the terms of the NDRA, manufacturers are required to initially submit all product and pricing information for all CODs under their labeler code(s), by national drug code (NDC), within 30 days of the end of the month and quarter in which the agreement is effective. For every month and quarter thereafter, product and pricing data is due within 30 days of the end of each respective monthly and quarterly period. If a manufacturer fails to submit timely information, or misreports information, CMS may be unable to establish accurate unit rebate amounts (URAs).

In addition to its use in rebate calculations, manufacturers' data is used for other purposes beyond the MDRP. For example, data reported to Medicaid for the purposes of establishing accurate rebate amounts is also used for the establishment of benchmark pricing for the Federal Upper Limit (FUL) reimbursement requirements for certain generic pricing under section 1927(e)(3) and (4) of the Act. In addition to its use in Medicaid, manufacturer data is used by the Health Resources and Services Administration (HRSA) for the 340B Drug Pricing Program. Specifically, pricing data submitted by manufacturers to Medicaid is used in the calculation of the HRSA 340B ceiling price, which is the maximum statutory price a manufacturer can charge a covered entity for the purchase of a COD. Medicare also uses the manufacturer data as a part of

the newly implemented Medicare Prescription Drug Inflation Rebate Program. For example, section 11102(a) of the Inflation Reduction Act of 2022 (IRA) (PL 117-169), added a new section 1860D-14B to the Act, which requires that the rebate amounts for the Medicare Part D Inflation Rebate Program be determined by the Secretary of HHS based on data collected by CMS from drug manufacturers.

Under section 1927(b)(3)(C)(i) of the Act HHS may issue civil money penalties (CMPs) if a manufacturer fails to submit timely pricing data.

MSIAA

Amendments Made by MSIAA to Section 1927 of the Act Regarding MDRP Drug Classification Enforcement and Penalties

Section 6 of MSIAA, titled, "Preventing the Misclassification of Drugs Under the Medicaid Drug Rebate Program," amended sections 1903 and 1927 to (1) modify the definitions for single source drug, innovator multiple source drug, and noninnovator multiple source drug, and (2) to provide the Secretary with additional compliance, oversight, and enforcement authorities to ensure compliance with program requirements with respect to manufacturers' reporting of drug product and pricing information, which includes the appropriate classification of a drug. Drug classification refers to how a drug should be categorized - as a single source drug, innovator multiple source drug, or noninnovator multiple source drug - for the purposes of determining the correct rebates that each manufacturer owes the states.

Prior to the enactment of MSIAA (enacted April 18, 2019), section 1927(k)(7)(A)(iv) of the Act defined a single source drug as a COD that is produced or distributed under an original new drug application (NDA). Section 1927(k)(7)(A)(ii) of the Act similarly defined an innovator multiple source drug as a multiple source drug that was originally marketed under an original NDA. A noninnovator multiple source drug was defined at section 1927(k)(7)(A)(iii) of the Act as a multiple source drug that is not an innovator multiple source drug. MSIAA made several revisions to these definitions, including adding a provision to codify CMS's existing policy to permit certain exceptions from the definitions if a narrow exception applies, as described in 42 CFR § 447.502 or any successor regulation. (Narrow exceptions are described in more detail in a later section.) Until the enactment of MSIAA, CMS only had the authority to impose penalties on manufacturers that failed to provide timely price information or provided false price information. Other than termination from the program, no specific authority existed for CMS to take any direct administrative actions against manufacturers that reported false drug product information or misclassified drugs.

MSIAA amended the Act to specify that the reporting of false information, including information related to drug pricing, drug product information, and data related to drug pricing or drug product information would be subject to CMPs. MSIAA also provided a specific new authority to issue CMPs related to manufacturers knowingly misclassifying a COD, such as by knowingly submitting incorrect drug product information.

Under MSIAA, if a manufacturer fails to correct the misclassification of a drug in a timely manner after receiving notification from CMS that the drug is misclassified, the manufacturer

must pay past unpaid rebates to the states for the misclassified drug, if applicable. The Secretary can take any or all of the following actions: correcting the misclassification, suspending the misclassified drug from the MDRP, imposing CMPs, or ultimately terminating the manufacturer's participation in the MDRP.

Guidance Published

CMS published guidance to manufacturers regarding compliance with drug pricing and drug product information under MSIAA in Manufacturer Release No. 113 on June 5, 2020. The program notice provided guidance regarding CMS implementation of MSIAA and explained how drug manufacturers could ensure they were complying with the drug pricing and drug product information reporting requirements in section 1927 of the Act. The guidance described several scenarios in which a given NDC may be potentially misclassified or misreported and provided information on steps that manufacturers should take to resolve the misclassification or misreporting. CMS also recently published two guidance documents related to narrow exceptions (described in more detail below), Manufacturer Release No. 120 and State Release No. 192, published on June 26, 2024.

Regulations to Implement MSIAA

Notice of Proposed Rulemaking

On May 23, 2023, the Federal Register displayed a CMS Notice of Proposed Rulemaking (NPRM), 88 FR 34238, CMS 2434-P, which proposed regulations to address drug misclassification, as well as drug product and pricing data misreporting by manufacturers, in accordance with MSIAA. Specifically, the NPRM proposed to do the following with regard to MSIAA:

- Codify processes to identify, notify, and correct a manufacturer's drug category misclassification;
- Define and describe what constitutes a misclassification;
- Codify actions that may be taken, or CMPs that may be imposed, if a manufacturer fails to correct the misclassification of a COD, including the suspension of the misclassified drug;
- Establish a definition of "drug product information";
- Establish a definition of "market date" for the purposes of determining a base date average manufacturer price (AMP) of a COD; and
- Codify the process by which the suspension of a manufacturer's NDRA would occur when a manufacturer fails to report timely drug pricing and drug product information to CMS.

After publication of the NPRM, there was a 60-day comment period that closed on July 25, 2023. CMS received 128 comments that were considered in the finalization of the rule. Of those comments, a number were related to the misclassification provisions.

Final Rule

On September 26, 2024, CMS published the 2024 Final Rule, Medicaid Program: Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program, 89 FR 79020, CMS-2434-F (2024 Final Rule), with an effective date of November 19, 2024. In the 2024 Final Rule, CMS describes how it will implement the statutory authorities granted under MSIAA to address issues related to incorrect reporting by drug manufacturers of drug product information in the Medicaid Drug Programs (MDP) system, as well as the misclassification of drugs. Specifically, the regulation:

- Defines the situations in which CMS considers a drug misclassified for the purposes of the MDRP, as well as other situations in which a manufacturer is paying rebates to states that are different from the rebates that are supported by the drug data being reported to MDP.
- Develops a process and timeline that CMS will use to notify the manufacturer that CMS has determined that a misclassification of a COD has occurred, and the process for correcting the misclassification.
- Codifies a manufacturer's obligation to pay unpaid rebate amounts to states due to the misclassification of CODs. Codifies the range of actions that CMS may take against a manufacturer that does not correct the misclassification after being notified, which include CMS correcting the misclassification, suspension of the drug and/or its manufacturer from the MDRP, exclusion of the misclassified drug from Medicaid payment, and imposition of CMPs.

In addition, CMS made two changes based on the comments that were received that are summarized below.

Misclassification: CMS received a number of comments in support of the proposed rule and others expressing concern about the ramifications of particular components of the suspension processes. CMS addressed these comments and noted that the proposed regulatory language was aligned with the requirements in the statute. However, CMS did make one change based on the comments; CMS added a sentence stating that if the manufacturer or CMS made changes to a manufacturer's reported product or pricing data to bring their data into compliance, the manufacturer will be given 30 days to certify those changes. CMS added this in response to comments that CMS should be consistent with prior guidance. CMS also noted in the preamble of the 2024 Final Rule that if the manufacturer does not complete the certification, CMS may take other authorized actions against the manufacturer.

Drug Product Information: CMS received comments regarding the definition of "drug product information." CMS proposed that the term include, but not be limited to, specific product information that manufacturers are required to provide but also include any other information deemed necessary by CMS to perform accurate URA calculations. Commenters noted parts of the proposed definition left the definition open-ended and could provide CMS a vehicle for arbitrary enforcement. In response to those comments, CMS removed the proposed language that made the definition open-ended.

Future Actions

CMS may now utilize the compliance options contained in the 2024 Final Rule to address situations in which a manufacturer has misclassified its CODs and misreported other pricing and product information to CMS. CMS may also use these tools to address late reporting by manufacturers. These tools will be vital in the effort to ensure accurate reporting by the manufacturers and to ensure that states receive the appropriate rebates. In future reports to Congress, CMS will report on any steps taken to reclassify such CODs as well as any actions taken by CMS to ensure manufacturers pay any rebate amounts which are subsequently owed as a result of the misclassification.

Disclosure of Expenditures

The statute requires CMS to provide in this report a disclosure of expenditures from the fund created in section 1927(b)(3)(C)(iv) of the Act, including an accounting of how such funds have been allocated and spent in accordance with such subsection. Since the regulations to implement MSIAA were just finalized in 2024, CMS has not imposed any CMPs in accordance with section 1927(c)(4)(B)(ii)(III) of the Act and thus has not collected any funds.

Actions Taken to Ensure Manufacturer Compliance with Reporting Requirements

CMS has taken a number of actions addressing drug misclassification and misreporting by manufacturers in other contexts, several of which are highlighted below.

Oversight of Manufacturer Reporting of CODs

Manufacturers sometimes attempt to report products to CMS for inclusion in the MDRP that do not satisfy the definition of a COD. Inclusion of those products could lead states to cover these products even though it is not mandated by section 1927 of the Act. However, if a product does not satisfy the COD definition, coverage of that product may be optional, and the product is not subject to the requirements of the MDRP. Because the requirements of the MDRP generally rely upon the status of a product as regulated by the Food and Drug Administration (FDA), it is important that CMS be able to identify the FDA's status of a drug to evaluate whether that product is subject to the MDRP.

Under the Federal Food, Drug, and Cosmetic Act, a manufacturer must list their marketed drugs with FDA.[2] To do so, the manufacturer submits certain Structured Product Labeling (SPL) information to the FDA for the manufacturer's marketed drugs.[3] The SPL contains information about the regulatory status of the drug, as identified by the manufacturer, which includes the marketing category of the drug (e.g., NDA, Abbreviated New Drug Application (ANDA), Biologics License Application (BLA), OTC Monograph Drug), the approved application

[2] See 21 U.S.C. 360(j); see also 21 CFR part 207.

[3] https://www.federalregister.gov/documents/2016/08/31/2016-20471/requirements-for-foreign-and-domestic-establishment-registration-and-listing-for-human-drugs

number, and other regulatory information. The Comprehensive NDC SPL Data Elements File is available for download from a public FDA website.[4]

CMS utilizes the information reported to the FDA to determine whether products should be included in the MDRP. To ensure that CMS has access to the information, from 2013 to 2014, CMS notified manufacturers of its plans to remove products reported for inclusion in MDRP if those products were not listed with the FDA as required. In 2014, CMS removed over 1,300 products from the CMS drug product file from over 125 manufacturers. Subsequently, many of these products were restored in the CMS drug product file when the manufacturer listed the drug product with the FDA.

CMS continues to monitor new NDC entries into the CMS drug product file to ensure they are listed with the FDA and has made modifications to MDP so the system performs an automated FDA listing check on drugs newly reported by a manufacturer. Specifically, upon a manufacturer's entering product data for a new drug into MDP, the system performs an automated validation to determine whether the new drug's NDC appears on FDA's published listing of marketed drugs. If it does not, the NDC goes into a holding status and the manufacturer is notified to either list the drug with the FDA or contact CMS for assistance.

CMS Added New Product Data Fields to the Reporting System

CMS also asks manufacturers to provide information to help confirm that a drug meets the COD definition. In 2014 CMS added several new data fields to the reporting system that manufacturers were required to report to CMS when submitting their drug product information. One of those new fields, the COD status field, identifies either the type of FDA approval (e.g., NDA, ANDA, and BLA) or other authority under which the drug is marketed (e.g., OTC monograph). The implementation of this new data field requires manufacturers to evaluate whether their product satisfied the definition of COD and if so, to identify by what means. The data field also provides information that the states can utilize to determine how a drug satisfies the definition of COD.

CMS Added Automated Validation of Newly Reported Drugs to the Reporting System

In December 2018, CMS added an enhanced, automated product data validation to the reporting system. After the newly reported drug passes the FDA listing validation described above, the CMS system compares reported data for the following data fields to information available for download from several FDA websites:[5]

- FDA application number or OTC monograph citation
- Drug type (i.e., prescription or OTC)
- COD status
    - Validation of COD status utilizes FDA-published data for Application Type and Marketing Category

By validating and evaluating these data fields, CMS is ensuring that manufacturers correctly

[4] https://www.fda.gov/industry/structured-product-labeling-resources/nsde

[5] https://www.fda.gov/industry/structured-product-labeling-resources/nsde; https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-data-files.

report data fields, including drug category. This ensures that CMS's calculation of the URA, which is provided to the states, is performed using the correct formulas.

Any newly reported NDC that fails the FDA listing validation described above or any of these other data field validations is placed into a "holding" status, cannot be initially certified by the manufacturer, and is not added to the MDRP drug list until all discrepancies are resolved. The drug is not considered to be reported to CMS and is out of compliance with CMS reporting requirements until the discrepancies are resolved and the manufacturer certifies the information. States may choose not to cover the drug in their Medicaid programs until the drug is actively in the system; this motivates manufacturers to correct the discrepancies.

Verification of Existing Drugs

In November 2021 CMS implemented MDP, a new reporting system which included new tools to increase CMS's ability to confirm that a drug reported to MDRP is listed with FDA and ensure manufacturer compliance with MDRP drug product data reporting requirements. For example, CMS is now able to perform quarterly automated verification of the active drugs already existing in the reporting system to verify that the drugs are listed with FDA. If any previously reported drug fails this verification process, the drug is identified as "out of compliance" and the manufacturer is prohibited from reporting pricing information until the compliance issue is resolved. Because manufacturers participating in the MDRP have specific price reporting requirements, the inability to report pricing information to CMS is significant motivation for manufacturers to ensure their drugs are listed with FDA. Additionally, CMS refers manufacturers whose pricing data submissions do not comply with reporting requirements to the Office of Inspector General for the Department of Health and Human Services.

There are approximately 29,000 drug products currently active in MDP, and there were no drugs identified as "out of compliance" with the FDA listing requirements as of November 2024.

Drug Classification and Narrow Exceptions to that Classification - 2016 Final Rule

In addition to actions taken by CMS described above, there have been other policy initiatives that had effects on the classification of drugs; in those instances, CMS has worked to ensure proper classification. For example, in 2016, CMS published a final rule with comment period[6] that implemented provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for CODs. The Affordable Care Act increased the minimum rebate percentage for most single source and innovator multiple source drugs from 15.1 percent of the AMP to 23.1 percent of AMP and increased the rebate percentage for noninnovator multiple source drugs from 11 percent of AMP to 13 percent of AMP. In response, the 2016 Final Rule created or modified regulatory definitions of single source drugs, innovator multiple source drugs and noninnovator multiple source drugs. The implementation of these provisions of the Affordable Care Act by extension impacted the classification of drugs and when such classification may be incorrect.

[6] https://www.federalregister.gov/documents/2016/02/01/2016-01274/medicaid-program-covered-outpatient-drugs

The 2016 Final Rule also created a "narrow exception" related to drug classification for situations when a drug approved under an FDA application that would otherwise classify it as an innovator drug, should be considered a noninnovator drug. MSIAA then incorporated this narrow exception into statute through the definitions of single source drug, innovator multiple source drug, and noninnovator multiple source drug in section 1927(k) of the Act. Generally, drugs approved for marketing by FDA under an NDA should be classified as single source drug or innovator multiple source drug, and therefore subject to a formula that results in a higher rebate than if the drug was classified as a noninnovator multiple source drug. Drugs that are approved under an ANDA may be classified as a noninnovator multiple source drug. However, there are some circumstances when a drug that is marketed under an NDA is more appropriately treated as a noninnovator multiple source drug and therefore subject to the lower rebate. To account for these circumstances, the 2016 Final Rule established a narrow exception to allow certain drugs that are marketed under an NDA to be classified as a noninnovator multiple source drug.

As discussed in the 2016 Final Rule, examples of drugs with NDA approvals which might be more appropriately treated as if they were approved under an ANDA and classified as noninnovator multiple source drugs are as follows:

- Certain parenteral drugs in plastic immediate containers, for which FDA required that an NDA be filed;
- Certain drugs approved under a paper NDA prior to the enactment of the Hatch-Waxman Amendments of 1984; and
- Certain drugs approved under certain types of literature-based 505(b)(2) NDA approvals after the Hatch-Waxman Amendments of 1984.

The 2016 Final Rule noted that a narrow exception will not be granted under the following circumstances:

- Drugs marketed under NDAs that were not approved under either the paper NDA process prior to 1984 or under certain types of literature based 505(b)(2) approvals, other than certain parenteral drugs in plastic immediate containers, for which FDA required that an NDA be filed; or
- Drugs that received patent protection or statutory exclusivity, regardless of whether the protection or exclusivity is currently in effect.

If a manufacturer believes that one of its drugs qualifies for a narrow exception, based on parameters outlined in the 2016 Final Rule, it may submit a request for the exception along with an explanation and documentation of how the drug satisfies the parameters described by CMS.

CMS has received requests for a narrow exception for approximately 600 individual drugs, approximately half of which were granted. If a request for a narrow exception is denied, and if a subsequent request for a reconsideration of that decision results in confirmation of that denial, the manufacturer is required to correct the drug category and pay the states any difference between previously paid rebates and those that would have been due under the correct drug category. CMS will be using the authority granted by MSIAA following the processes described in the 2024 Final Rule to ensure manufacturers make the appropriate data changes in the MDP. Manufacturers are responsible to reconcile rebate payments with the states that result from changes to the URA due to the correction of any misclassification.

Subsequent Actions

The 2016 Final Rule also allowed CMS to take additional actions to ensure drugs were not misclassified. After the April 1, 2016 effective date of the 2016 Final Rule, manufacturers had one year to either correct the drug classification of a misclassified drug or to request a narrow exception. CMS began an initiative to contact manufacturers that were misreporting drug product information after the March 31, 2017, deadline. This included misreporting of drug category (i.e., single source drug, innovator multiple source drug, or noninnovator multiple source drug), drug type (i.e., prescription or OTC), COD status, and FDA application number. CMS successfully resolved numerous instances of misreporting during that effort.

CMS Review of Manufacturers Entering the MDRP or Rejoining the MDRP after a Period of Non-Participation

When a manufacturer first enters the program, it must execute a new NDRA. When a request for a new NDRA is submitted, CMS staff reviews and evaluates the application, including the list of drugs that will be subject to the NDRA. Prior to 2021, CMS required a manufacturer to provide most product data for their drugs on an Excel spreadsheet for review by CMS. If discrepancies were identified, CMS worked with the manufacturer until the manufacturer understood how to correctly report the data. Since the implementation of the new MDP system in 2021, manufacturers now directly enter product data related to all of the drugs associated with the new NDRA into the MDP system. That data goes through the same FDA listing and validation process as every new drug entered in the system, enabling CMS to proactively evaluate a manufacturer's data.

Additionally, if a previously participating manufacturer requests to re-enter the MDRP after a period of nonparticipation, the manufacturer must request reinstatement and execute a new NDRA. When a manufacturer requests reinstatement into the MDRP, it must review all of its product data that exists in the reporting system, correct any errors or omissions, and add any new drugs that it now markets that are required to be reported in accordance with section 1927 of the Act. The newly reported drugs go through the automated FDA listing verification and validation process. Manufacturers are not issued a new NDRA until the data has been verified and validated.

Ongoing Compliance Efforts Regarding Data Submission

Before the issuance of the recent 2024 Final Rule codifying the MSIAA statutory requirements, CMS was taking steps to ensure manufacturers are reporting product and pricing data correctly. As previously discussed, section 1927(b)(3) of the Act requires manufacturers to report specific information on its CODs on a monthly and quarterly basis to CMS. CMS evaluates manufacturers' CODs via monthly and quarterly reporting to ensure that a manufacturer is fulfilling these requirements by the prescribed deadlines. If CMS identifies data that is unreported, or data that is reported late, the manufacturer is sent an email notifying them of potential non-compliance. The manufacturer is given 15 days to respond to CMS with either a valid explanation of why the data is not required, or to come into compliance. A manufacturer

that continues to be non-compliant with the deadlines is further evaluated and may be subject to termination from the MDRP.

Summary of CMS Actions to Improve Oversight of Manufacturer Drug Classification

Date Initiated	Activity/Action taken
September 2014	CMS removed 1300 products from its drug file that were not listed with FDA as required by FDA regulation.
July 2014	CMS added several new data fields to its reporting system that manufacturers were required to report when submitting their drug product information to aid with CMS oversight of manufacturer reporting.
May 2016	CMS issued manufacturer guidance on the narrow exceptions process within the MDRP.
April 2016	Effective date of Final Rule implementing provisions of the Affordable Care Act, including the establishment of a "narrow exception" process that, in limited circumstances, allows a drug that would otherwise be treated an innovator drug to be treated as if it was a noninnovator drug.
December 2018	CMS implemented enhanced automated validation to the CMS reporting system to validate certain reported data that manufacturers provide to CMS by using FDA files.
April 2019	MSIAA was enacted, providing additional enforcement authorities to CMS.
June 2020	CMS issued manufacturer guidance describing MSIAA authorities and describing how manufacturers should determine compliance with obligations under the MDRP.
November 2021	CMS implemented MDP, a new reporting system with enhanced capabilities to prevent manufacturer misclassification and misreporting and to automate verification of the active drugs already existing in the reporting system against FDA databases.
May 2023	Notice of Proposed Rulemaking proposed regulations to address drug misclassification, as well as drug product and pricing data misreporting by manufacturers, in accordance with MSIAA.
June 2024	CMS issued additional manufacturer and state guidance regarding the narrow exception process.
November 2024	Effective date of Final Rule, Medicaid Program: Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program.

Summary

CMS has implemented and provided oversight of the MDRP since 1991. The program utilizes manufacturer-reported product and pricing information to implement the statutory and regulatory requirements. Manufacturer pricing information and drug product information are used to assist with the MDRP and for ensuring CMS has accurate financial information regarding expenditures. Additionally, manufacturer information is used in other areas of Medicaid, by HRSA, and by Medicare in connection with the Medicare Part D Inflation Rebates Program.

CMS has systematically improved oversight over the MDRP by enhancing validation in the MDRP reporting system and by performing reviews of manufacturer-reported data. Until the implementation of MSIAA, CMS had limited authority to take direct administrative enforcement action against a manufacturer if misclassification of a drug or misreporting of information was found.

As described in detail previously in this Report, MSIAA has provided several new enforcement authorities to CMS in section 1927 of the Act. The regulations to implement these new authorities became effective on November 19, 2024. CMS is continuing to evaluate manufacturer compliance and contacting manufacturers when discrepancies are identified. If a manufacturer does not address identified discrepancies and correct misreporting, including misclassification, CMS now has the authority to take enforcement action that is no longer limited to termination from the MDRP.