ROPES & GRAY

ALERT

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A New Wave of Agency Action Around Drug Pricing: CMS Proposes Sweeping Medicaid Drug Rebate Program Rule

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I. Introduction

On May 26, 2023, the Centers for Medicare & Medicaid Services ("CMS") published a proposed rule in the *Federal Register* entitled "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program" (the "Proposed Rule").[1] If finalized, the Proposed Rule would introduce changes that would significantly impact manufacturers' obligations and potential enforcement against manufacturers under the Medicaid Drug Rebate Program (the "MDRP").

Under the MDRP, participating manufacturers are required to enter into a National Drug Rebate Agreement ("NDRA") with the Secretary of the U.S. Department of Health and Human Services ("HHS") in exchange for state Medicaid coverage of their covered outpatient drugs ("CODs").[2] Under an NDRA, and in accordance with section 1927 of the Social Security Act (the "Act"), manufacturers must pay rebates to states to help partially offset the federal and state costs of the CODs dispensed and paid for under state Medicaid plans. Under the MDRP, manufacturers have reporting obligations within statutorily defined time frames—for example, manufacturers must submit and certify average manufacturer price ("AMP") and best price data each quarter.[3] Many of the proposed changes in the Proposed Rule clarify or alter some of these reporting obligations and the consequences of failure to timely and accurately report.

This Alert provides an overview of proposed changes to the MDRP in the Proposed Rule and offers key considerations for manufacturers. The proposed changes include the following:

- Introducing a new definition of "misclassification" in the MDRP, as well as processes for identification and notification of manufacturers of misclassifications, manufacturers' payment of unpaid rebates due to misclassification, and other enforcement measures available to CMS;
- Modifying the determination of "best price" by requiring manufacturers to aggregate or "stack" all price concessions, even when provided to different entities;
- Revising several definitions, including those for CODs, manufacturer, and market date, which has significant implications for manufacturers under the MDRP;
- Introducing a new annual drug price verification survey that would target certain manufacturers and/or wholesalers and impose reporting obligations; and
- Implementing several other regulatory changes, such as setting a time limitation on manufacturer audits, requiring drug cost transparency in managed care contracts, and introducing a process through which NDRAs may be suspended for late price and drug production information reporting.

Comments on the Proposed Rule are due July 25th—*i.e.*, 60 days after the May 26, 2023 publication of the Proposed Rule in the *Federal Register*.

II. Drug Misclassification in the MDRP

MDRP rebate calculations depend, in part, on how a drug is classified—as a single source drug ("S drug"), an innovator multiple source drug ("I drug"), or a noninnovator multiple source drug ("N drug"), generally with higher rebates for S and I drugs.[4] Consequently, under the MDRP, manufacturers must classify and report drug classification information to

CMS. CMS reports that many manufacturers continue to misreport drugs, often reporting S or I drugs as N drugs, or pay different rebate amounts other than what is supported by the drug classification.[5]

In 2019, Congress passed the Medicaid Services Investment and Accountability Act of April 2019 ("MSIAA"), which included a section dedicated to "Preventing the Misclassification of Drugs Under the [MDRP]."[6] This section of the MSIAA amends sections 1903 and 1927 of the Act to specify definitions for multiple source drug, single source drug, and innovator multiple source drug and also provided the Secretary of HHS with certain compliance, oversight, and enforcement authority to ensure manufacturers' compliance with reporting obligations under the MDRP. In the Proposed Rule, CMS seeks to implement and codify the statutory changes enacted pursuant to the MSIAA with proposed changes regarding (i) the identification of a misclassification and notification to manufacturers to correct a misclassification, (ii) manufacturer payment of unpaid rebates due to misclassification, (iii) agency authority to correct misclassifications and additional penalties for drug misclassification, and (iv) transparency with the public regarding drug misclassifications.

a. Identification and Notification to Manufacturer to Correct Misclassification

First, CMS proposes to define misclassification in the MDRP as occurring when "a manufacturer has: (i) [r]eported and certified to the agency its drug category or drug product information related to a [COD] that is not supported by the statute and applicable regulations; or, (ii) [r]eported and certified to the agency its drug category or drug product information that is supported by the statute and applicable regulations, but pays rebates to the States at a level other than that associated with that classification."[7] In the Proposed Rule, CMS emphasizes that the implementing statute expressly indicates that "a misclassification can occur without regard to whether the manufacturer knowingly made the misclassification or should have known that the misclassification was made."[8]

As an example, CMS says that a COD is considered misclassified if it is reported to CMS as an N drug when, according to CMS as based on its application of relevant statutes and regulations, the COD should be classified as an S drug. Furthermore, under the Proposed Rule, misclassification is not limited to drug category but applies to any incorrectly used "drug product information" relating to a COD. CMS proposes that the definition of "drug product information" includes but is not limited to "National Drug Code (NDC), drug name, units per package size (UPPS), drug category ("S", "I", "N"), unit type (for example, TAB, CAP, ML, EA), drug product type (prescription, over-the-counter), base date AMP, therapeutic equivalent code (TEC), line extension indicator, 5i indicator and route of administration, if applicable, U.S. Food and Drug Administration (FDA) approval date, FDA application number or OTC monograph citation as applicable, market date, COD status, and any other information deemed necessary by the agency to perform accurate unit rebate amount (URA) calculations."[9] Consequently, CMS states that "report[ing] and certif[ying] an incorrect base date AMP to calculate its inflation penalty rebates" would also be considered a misclassification, as the manufacturer is using drug product information not supported by the statute and applicable regulations.[10] In the Proposed Rule, CMS also applies its authority under the misclassification provisions to the narrow exception context,[11] stating that CMS would be able to pursue penalties against manufacturers that do not change their drug classification when their narrow exception request has been denied by CMS.[12] Taken together, the scope of agency-defined misclassification is expansive—any incorrectly used drug product information could trigger enforcement and potential penalties under the misclassification provisions.

CMS also proposes a process by which CMS would notify manufacturers of a drug misclassification. Under the Proposed Rule, after determining that a misclassification has occurred, CMS "[would] send written and electronic notification of [the] misclassification to the manufacturer of the [COD], which may include a notification that past rebates are due." From the date of notification, the manufacturer would be allotted 30 calendar days to "provide [CMS] with [any] drug product and drug product information needed to correct the misclassification of the [COD] and calculate rebate obligations [that are] due," which must include best price information, if applicable, for the rebate periods during which the misclassification occurred.[13] During this 30-day time period, the manufacturer would also be required to certify the applicable price and drug product data provided to CMS.[14]

b. Manufacturer Payment of Unpaid Rebates Due to Misclassification

Second, CMS sets out a proposed process for manufacturers to pay unpaid rebates to the state for misclassified drugs after identification by CMS and notification of the manufacturer. Specifically, CMS proposes that a manufacturer must pay each state, for each period during which the drug was misclassified, the difference between (i) the per unit rebate amount ("URA") paid by the manufacturer for the COD when the COD was misclassified and (ii) the per URA that the manufacturer would have paid if the COD were classified correctly, multiplied by the total units of the COD paid for under the state Medicaid plan in each period.[15] The time frame within which CMS proposes that such unpaid rebates must be paid is 60 calendar days from the date that notice is sent by CMS to the manufacturer indicating that a COD is misclassified. Within this same time frame, CMS also proposes that manufacturers must provide documentation to CMS that all past due rebates have been paid. Depending on the misclassification made and the number of periods for which a drug was misclassified, a 60-day time frame to pay these unpaid rebates could place burden on manufacturers.

c. Agency Authority to Correct Misclassifications and Additional Penalties for Drug Misclassification

Third, CMS proposes to implement a set of enforcement measures that CMS may use in the event that a manufacturer fails to do at least one of the following: (i) correct the misclassification within 30 calendar days from the date of notification, (ii) certify applicable pricing and drug product data, and/or (iii) pay the unpaid rebates that are due as a result of the misclassification within 60 calendar days from the date of notification.[16] Specifically, CMS proposes that if a manufacturer fails to correct the misclassification within 30 calendars days from the date of notification, then CMS may correct the misclassification of the drug in the system on behalf of the manufacturer, using any pricing and drug product information that may have been provided by the manufacturer. Under the Proposed Rule, CMS also may take other actions, in response to any of the failures described above, including (i) suspending the misclassified drug and the drug's status as a COD under the manufacturer's NDRA, (ii) excluding the misclassified drug from Federal Financial Participation ("FFP") pursuant to section 1903(i)(10)(E) of the Act,[17] and/or (iii) imposing a civil monetary penalty for each rebate period during which the drug is misclassified, up to a maximum cap outlined in the Proposed Rule.[18] In addition to these actions expressly outlined in the Proposed Rule, CMS also proposes that CMS may take other actions or seek additional penalties available under any other provision of law against manufacturers that misclassify their drugs, which may include referral to the HHS Office for Inspector General and termination from the MDRP.[19]

d. Transparency of Manufacturer Misclassification

Finally, in furtherance of a statutory requirement that requires information on CODs that have been identified as misclassified to be reported annually to Congress and made available to the public on a public website, CMS proposes to implement a new regulatory provision under which CMS would make publicly available an annual report listing the CODs that were identified as misclassified during the previous year, with accompanying information relating to any steps taken by CMS to reclassify the CODs and ensure manufacturers paid any additional rebate amounts due as a result of the misclassifications.

III. "Stacking" for the Determination of Best Price

The Proposed Rule aims to modify the determination of Medicaid "best price" by requiring manufacturers to aggregate, or "stack," all price concessions (*i.e.*, cumulative discounts, rebates, or other arrangements) to generate a final price realized by the manufacturer for a particular unit of a COD.[20] Under the Proposed Rule, if a manufacturer offers multiple discounts to two entities for the same drug transaction, all discounts related to that transaction that adjust the price available from the manufacturer would be considered in the final price of that drug when determining best price. The stacking requirement would apply even if the entity did not buy the drug directly from the manufacturer, thus increasing the Medicaid drug rebate to the state and federal government.[20]

The Proposed Rule responds to recent case law, which emphasized CMS's lack of "authoritative guidance" on discount stacking. In *United States ex rel. Sheldon v. Allergan Sales, LLC,* the issue was whether a manufacturer violated the False Claims Act ("FCA") by failing to stack discounts provided to separate entities for purposes of determining the best price.[22] The district court held that the FCA elements of falsity and knowledge were not met because the manufacturer's interpretation that stacking was not required was "objectively reasonable" and CMS's rule had not explicitly prohibited it. On appeal, a panel of the Fourth Circuit affirmed the district court decision because "a defendant cannot act 'knowingly' . . . if it bases its actions on an objectively reasonable interpretation of the relevant statute when it has not been warned away from the interpretation by authoritative guidance."[23] In a 7–7 split decision, an *en banc* Fourth Circuit affirmed the district court but vacated the prior panel decision.[24] The Proposed Rule, if finalized, may serve as a type of authoritative guidance that could have been relevant in the *Sheldon v. Allergan* litigation. There are likely to be questions from industry regarding whether this Proposed Rule comports with the Medicaid drug rebate statutory requirements regarding best price reporting.

IV. Definitional Changes

a. Covered Outpatient Drugs

The Proposed Rule's definition of COD excludes any drug "provided as part of [certain] services, and for which payment may be made as part of that service instead of as a direct reimbursement for the drug."[25] The Proposed Rule then clarifies that "direct reimbursement" encompasses both reimbursement for a drug alone and reimbursement for a drug plus the service, in one inclusive payment, if the drug and the itemized cost of the drug are separately identified on the claim.[26] This agency proposal, if finalized, would expand the universe of qualifying CODs and, seemingly, would mean that whether a drug is considered a COD depends, in part, upon how the provider codes it.

b. Manufacturer

The Proposed Rule embraces an "all-or-nothing" policy for labelers of manufacturers. Under the Proposed Rule, CMS would amend the term "manufacturer" to include "all associated entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control, must each maintain an effectuated rebate agreement."[27] All labelers associated or affiliated with a manufacturer would need to have a rebate agreement in effect with the Secretary of HHS in order for any of that manufacturer's CODs to be eligible for FFP.[28] If a manufacturer with a rebate agreement in effect:

1. acquires or purchases another labeler,
2. acquires or purchases covered outpatient drugs from another labeler code, or
3. forms a new subsidiary,

then the manufacturer would need to ensure that a signed rebate agreement is in effect for these entities or CODs within the first 30 days of the next full calendar quarter beginning at least 60 days after the acquisition, purchase, asset transfer, or formation of the subsidiary.[29] Similarly, termination from FFP by one labeler or the failure of a labeler to have a rebate agreement in effect would result in termination of all the manufacturer's associated labelers from the program.[30]

c. Market Date

The market date of a drug, for purposes of establishing the base date AMP quarter, is critical in the calculation of inflation rebates that manufacturers owe on their CODs.[31] The Proposed Rule would modify the definition of market date to reflect the date on which the COD was first *sold* by any manufacturer.[32] CMS asks for comments on what qualifies as "sold" for purposes of establishing the market date.

d. Internal Investigation

Under the Act, manufacturers generally have a 12-quarter window to make restatements, except in defined circumstances, which include restatements as a result of an internal investigation. The Proposed Rule defines an internal investigation as "a manufacturer's investigation of its AMP, best price, customary prompt pay discounts or nominal prices that have been previously certified in the [MDRP] that results in a finding made by the manufacturer of fraud, abuse, or violation of law or regulation."[33] CMS explains that it intends for this rule to allow for revisions to previously reported data in the context of acquired drugs, although, in order for CMS to consider a manufacturer's requested exception to the 12 quarter rule, the manufacturer would have to find an indication of a violation of statute or regulation by the prior manufacturer and make the data available to CMS to support its findings of such a violation.[34] Under the Proposed Rule, mere disagreement with the prior manufacturer's pricing calculations would not be a legitimate justification for an exception to the 12-quarter rule.[35]

e. Vaccine

Vaccines are excluded from the definition of COD under the Act and thus are not subject to rebates.[36] There is currently no applicable statutory or regulatory definition of a vaccine in the Act.[37] The Proposed Rule would define a "vaccine"—for purposes of the MDRP only—as a product that is administered prophylactically to "induce active, antigen-specific immunity for the prevention of one or more specific infectious diseases and is included in a current or previous FDA published list of vaccines licensed for use in the United States."[38] Other biologics that do not meet this definition would presumably be treated as CODs for purposes of the MDRP.

f. Noninnovator Multiple Source Drug

Noninnnovator multiple source drugs, or N drugs, were historically multiple source drugs that were either unapproved or approved under an Abbreviated New Drug Application ("ANDA").[39] The Proposed Rule directs manufacturers to categorize as "N drugs" all CODs that are neither single source drugs nor innovator multiple source drugs, regardless of whether they meet the definition of a noninnovator multiple source drug, thus expanding the reach of rebates for this category of products.[40]

V. Other Proposed Changes

a. ***Drug Price Verification Survey Process:*** CMS, pursuant to its authority under section 1927(b)(3)(B) of the Act, proposes to implement a process to survey manufacturers and wholesalers that directly distribute their CODs in order to verify prices that are reported under the MDRP.[41] CMS says that the purpose of this survey is to allow states to better understand how COD prices are derived, particularly as the types of drugs paid for by Medicaid, manufacturers' pricing structures for these drugs, and methods for distribution have evolved substantially since the inception of the MDRP.[42] Manufacturers subject to reporting requirements would need to disclose various information, much of which is historically proprietary and confidential. CMS states that the survey would first focus on CODs with the highest Medicaid spending.[43] CMS also emphasizes that selection of a drug to be surveyed would not be done for the purposes of affecting its coverage under Medicaid.[44]

b. ***12-Quarter Rebate Audit Time Limitation:*** Under section 1927(b)(2)(A) of the Act, states must invoice manufacturers for rebates based on utilization of the manufacturer's drugs in a particular quarter no later than 60 days after the end of each quarter. Manufacturers may then audit state utilization data for their CODs;[45] if there are discrepancies on the invoice, then the manufacturer can submit a Reconciliation of State Invoice ("ROSI") form or Prior Quarter Adjustment Statement ("PQAS") to the state, with an explanation of the reasons for any adjustments.[46] Currently, there are no time limits on a manufacturer's initiation of a dispute concerning state utilization data on a rebate invoice. According to CMS, some manufacturers initiate disputes dating back many

years.[47] In order to "promote the timely identification of outstanding disputes" and to ensure that resources are efficiently allocated to the resolution of recent disputes, CMS proposes to "limit[] the period for manufacturers to initiate disputes, hearing requests and audits concerning State-specific COD utilization data to 12 quarters from the last day of the quarter from the date of the State invoice."[48] This would only apply to disputes regarding state drug utilization data on state rebate invoices and not to other change requests, such as change requests relating to COD Status, Market Date, and Base Date AMP.[49]

c. ***Beneficiary Identification Number and Processor Control Number ("BIN/PCN") on Medicaid Managed Care Cards:*** BIN and PCN numbers are used by health plans to identify a patient's prescription health insurance and benefits. Currently, Medicaid-specific BIN, PCN, and group numbers are not always placed on Medicaid managed care plan identification cards and thus it can be difficult to determine from a Medicaid managed care beneficiary's identification card whether the beneficiary is covered under a Medicaid managed care plan or some other non-Medicaid coverage. CMS therefore proposes to require Medicaid managed care organizations ("MCOs"), prepaid inpatient health plans ("PHIPs"), and prepaid ambulatory health plans ("PAHPs") that provide coverage of CODs to assign and exclusively use unique Medicaid BIN, PCN, and group number identifiers for all Medicaid managed care beneficiary identification cards for pharmacy benefits.[50] This new requirement would ensure that claims are billed and paid for appropriately for Medicaid managed care beneficiaries. CMS believes that these proposals, if implemented, also would help mitigate the risk of duplicate discounts under the 340B program by allowing for easier identification of Medicaid managed care claims.

d. ***Drug Cost Transparency in Medicaid Managed Care Contracts:*** Many MCOs, PHIPs, and PAHPs contract with subcontractors, such as pharmacy benefit managers ("PBMs"), to administer the Medicaid drug benefit. Often, managed care plans are unaware of how much the plan pays for the COD dispensed to the patient and how much is paid to the PBM for administrative fees related to the COD benefit. The difference between the amount a PBM charges a managed care plan for a drug claim and the amount paid by a PBM to a pharmacy for the claim, also known as the "spread" or "spread pricing," is only known to the PBM, unless disclosure is specifically required by a state Medicaid program or the managed care plan itself.[51] To increase transparency and accountability related to the payment for CODs, CMS proposes that contracts between managed care plans and any subcontractor for the delivery or administration of CODs must require the subcontractor to report separately certain expenses and costs above the actual cost of the prescription and dispensing fee.[52]

e. ***Rescission of Revisions to Best Price and AMP Patient Assistance Program Provisions:*** In 2020, CMS finalized its proposed revisions to regulations relating to PBM accumulator adjustment programs, providing that manufacturers' financial assistance payments to patients to offset the patient cost obligation of certain drugs would be excluded "only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient."[53] Given the U.S. District Court for the District of Columbia's decision to vacate this rule in *Pharmaceutical Research and Manufacturers of America vs. Becerra*,[54] CMS proposes to rescind its prior patient assistance exclusion rule revisions that would have impacted best price and AMP calculations in connection with PBM accumulator adjustment programs.[55]

f. ***Suspension of Manufacturer NDRA for Late Reporting of Pricing and Drug Production Information:*** CMS proposes to implement a process by which a manufacturer's NDRA would be suspended if the manufacturer fails to report timely information, including drug pricing and drug product information. Specifically, CMS would provide written notification to the manufacturer in the event that the manufacturer fails to provide timely information.[56] If a manufacturer failed to provide such information to CMS within 90 calendar days of the date of such notice, the agency would suspend the manufacturer's NDRA for all CODs furnished after the end of the 90-day calendar period, meaning that the manufacturer's CODs would no longer be eligible for Medicaid coverage or reimbursement and Medicaid FFP.[57] The suspension would continue until such information was reported in full and certified, with a minimum suspension period of 30 calendar days.[58] CMS proposes that

continued suspension could result in termination from the MDRP for cause. Of note, CMS states that in the event of a suspension, the NDRA would still remain in effect for purposes of Medicare Part B reimbursement and the 340B Drug Pricing Program.[59]

g. ***Removal of Manufacturer Rebate Cap:*** To conform with statutory amendments to section 1927(c)(2)(D) of the Act made pursuant to section 9816 of the American Rescue Plan Act of 2021, which sunsets the limit on maximum rebate amounts for single source and innovator multiple source drugs, CMS proposes to amend corresponding regulatory provisions to state that the current limit on maximum rebate amounts for all drugs (*i.e.,* the 100% AMP cap limit) ends on December 31, 2023.[60]

h. ***Conditions Relating to Physician-Administered Drugs:*** Under section 1927(a)(7) of the Act, states are required to provide for the collection and submission of utilization data and coding for CODs that are a single source or multiple source drug that is a "top 20 high dollar volume physician-administered drug on a published list . . . that the Secretary may specify."[61] CMS now proposes to require that states collect NDC information on *all* covered outpatient single and multiple source physician-administered drugs and that states invoice for rebates for all such drugs to receive FFP and secure manufacturer rebates.[62]

i. ***Request for Information on Requiring a Diagnosis on Medicaid Prescriptions:*** While Medicaid payment is limited to CODs used for a "medically accepted indications," there are currently no systems in place to determine whether a COD is used for a medically accepted indication.[63] CMS therefore is requesting comments on the potential impact of requiring that a patient's diagnosis be included on a prescription as a condition of receiving Medicaid FFP for that prescription.[64]

VI. Conclusion

CMS's Proposed Rule is sweeping in nature and addresses many critical aspects of the MDRP operation, including by proposing significant changes to manufacturing reporting responsibilities and prospective liability. It also would impose transparency and/or reporting requirements on various supply chain stakeholders.

If you have any questions regarding the Proposed Rule, please do not hesitate to contact one of the authors or your regular Ropes & Gray advisor.

1. Centers for Medicare & Medicaid Services, *Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program*, 88 Fed. Reg. 34238 (May 26, 2023).
2. 42 U.S.C. § 1396r–8(a).
3. 42 U.S.C. § 1396r–8(b)(3).
4. The term "single source drug" is statutorily defined as "covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug …, which is produced or distributed under a new drug application approved by the U.S. Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation)).Such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the Food and Drug Administration."42 U.S.C. § 1396r–8(k)(7)(A)(iv).The term "innovator multiple source drug" is statutorily defined 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 (as described in section 447.502 of title 42, Code of Federal Regulations (or any successor regulation))."42 U.S.C. § 1396r–8(k)(7)(A)(ii).The term "noninnovator multiple source drug" is statutorily defined as "a multiple source drug that is not an innovator multiple source drug."42 U.S.C. § 1396r–8(k)(7)(A)(iii).
5. 88 Fed. Reg. 34239.
6. Medicaid Services Investment and Accountability Act of 2019, Pub. L. No. 116-16, 133 Stat. 859 (2019).
7. 88 Fed. Reg. 34293.
8. 88 Fed. Reg. 34262.
9. 88 Fed. Reg. 34291.
10. *Id.*
11. Under section 1927(k)(7) of the Act, manufacturers may request that certain drugs produced or distributed under a new drug application ("NDA") approved by the U.S. Food and Drug Administration be treated instead as if they were approved under an abbreviated new drug application and classified as a noninnovator multiple source drug.The narrow exception generally applies only to "paper NDAs" approved prior to the enactment of the Hatch-Waxman Amendments and drugs approved under certain types of literature-based 505(b)(2) NDA approvals.81 Fed. Reg. 5170, 5191 (Feb. 1, 2016).
12. 88 Fed. Reg. 34282.
13. 88 Fed. Reg. 34293.
14. *Id.*
15. 88 Fed. Reg. 34263.
16. *Id.*
17. FFP is the "Federal Government's share of a State's expenditures under the Medicaid program."42 C.F.R. § 400.203.
18. "Civil monetary penalt[ies] for each rebate period during which the drug is misclassified [may] not exceed an amount equal to the product of the total number of units of each dosage form and strength of such misclassified drug paid for under any State Plan during such a rebate period; and 23.1 percent of the AMP for the dosage form and strength of such misclassified drug for that period."88 Fed. Reg. 34264.
19. *Id.* The authority to terminate a manufacturer from the MDRP is pursuant to section 1927(b)(4)(B)(i) of the Act, which provides that the Secretary may terminate a manufacturer from the MDRP for violation of the rebate agreement or other good cause.
20. 88 Fed. Reg. 34260.
21. *Id.*
22. *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 351, 354 (4th Cir. 2022), *rev'd en banc* granted, No. 20-2330, 2022 WL 1467710 (4th Cir. May 10, 2022).
23. *United States ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 348 (4th Cir. 2022).
24. 88 Fed. Reg. 34260.
25. 88 Fed. Reg. 34291.
26. *Id.*
27. "All associated entities of the manufacturer that sell prescription drugs, including, but not limited to, owned, acquired, affiliates, brother or sister corporations, operating subsidiaries, franchises, business segments, part of holding companies, divisions, or entities under common corporate ownership or control." 88 Fed. Reg. 34292.
28. 88 Fed. Reg. 34243.
29. *Id.*
30. *Id.*

31. 88 Fed. Reg. 34243.
32. CMS clarifies that the market date is *not* the first date that the COD was available for sale. 88 Fed. Reg. 34257.
33. 88 Fed. Reg. 34253.
34. *Id.*
35. 88 Fed. Reg. 34254.
36. 88 Fed. Reg. 34244.
37. 88 Fed. Reg. 34258
38. 88 Fed. Reg. 34259.
39. CMS maintains that "other drugs" and "noninnovator multiple source drugs" are not synonymous.88 Fed. Reg. 34266.
40. *Id.*
41. 88 Fed. Reg. 34268.
42. 88 Fed. Reg. 34245.
43. 88 Fed. Reg. 34271.
44. 88 Fed. Reg. 34268.
45. 42 U.S.C. § 1396r–8(b)(2)(B).
46. 88 Fed. Reg. 34266.
47. 88 Fed. Reg. 34267.
48. *Id.*
49. *Id.*
50. 88 Fed. Reg. 34246.
51. *Id.*
52. 88 Fed. Reg. 34249, 34252.
53. 88 Fed. Reg. 34261.
54. *Pharmaceutical Research and Manufacturers of America vs. Becerra*, Civil Action No. 1:21-cv-1395 (CJN) (D.D.C. May 17, 2022)
55. 88 Fed. Reg. 34261.
56. 88 Fed. Reg. 34294.
57. 88 Fed. Reg. 34264.
58. *Id.*
59. *Id.*
60. 88 Fed. Reg. 34265.
61. 88 Fed. Reg. 34245.
62. 88 Fed. Reg. 34245, 34246.
63. 42 U.S.C. § 1396r–8(k)(6).
64. 88 Fed. Reg. 34247.