Medicaid Drug Rebate Program (MDRP) proposed rule could impact 340B covered entities

August 2023

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The title of a recent proposed rule put out by the Centers for Medicare and Medicaid Services (CMS) does not exactly roll off the tongue — "Medicaid Program; Misclassification of Drugs, Program Administration and Program Integrity Updates Under the Medicaid Drug Rebate Program." And it is not obvious that the proposed rule should be something 340B covered entities care about. However, buried in the text of CMS's May 26, 2023, proposed rule are several regulatory changes that, if enacted, would require many 340B entities to take action to adjust their operations.

At issue is the fact that the federal 340B program and the MDRP are intertwined such that changes directed at the MDRP can have downstream impacts on the 340B program. We have highlighted four changes proposed by CMS that 340B covered entities should take note of.

Clarification of the definition of covered outpatient drug (COD)

The definition of COD determines which drugs are subject to 340B program rules. Under the current COD definition, many providers consider drugs that are reimbursed by Medicaid under bundled payments to be non-340B drugs (i.e., not subject to the group purchasing organization (GPO) prohibition), because drugs covered by payments made as part of a service instead of by a direct reimbursement for the drug are not considered CODs.

CMS is proposing to revise the definition of COD to clarify that the reimbursement for the drug may be a direct reimbursement if the drug and its itemized cost are separately identified on the claim submitted to the Medicaid payer. Put differently, a drug could be considered a COD (i.e., a 340B drug) on the basis that the entity submits a separate charge for the drug on the claim it submits to Medicaid payers, even if it is reimbursed by Medicaid as part of a bundled rate.

For covered entities subject to the GPO prohibition, this proposed rule raises some key considerations for covered entities, including:

- How does your facility define covered outpatient drugs (i.e., 340B drugs) in policies and procedures?
- Does your facility separately charge for drugs that are currently excluded from the definition of COD in your policies and procedures?
- How do you currently blacklist drugs in your split-billing/third-party administrator (TPA) software?
- Are you blacklisting drugs that you also separately identify on claims?
- Do you have a non-pharmacy buyer (e.g., materials management) purchasing any of these blacklisted products?
- What would it mean for you (e.g., first purchase wholesale acquisition cost (WAC) in virtual inventory models) to have to start treating separately identified drugs as CODs?

Amendments to the definition of "vaccine"

The Social Security Act specifically excludes vaccines from the definition of COD for purposes of the MDRP, but MDRP has historically had no formally established regulatory definition of the term "vaccine." CMS is proposing the following definition:

> "Vaccine means a product that is administered (1) prophylactically (2) to induce active, antigen-specific immunity (3) for the prevention of one or more specific infectious diseases and (4) is included in a current or previous FDA published list of vaccines licensed for use in the United States."

Under this proposed rule, pharmaceuticals that were previously considered vaccines may no longer be eligible for exclusion from the definition of COD, particularly those considered non-prophylactic. Covered entities subject to the GPO prohibition should be evaluating:

- What kind of purchasing account (e.g., 340B, GPO, WAC) your facility currently uses to purchase vaccines
- How your facility determines whether a drug is a vaccine for purposes of excluding it from the definition of COD in your policies and procedures

New requirements regarding Medicaid rebate eligibility for physician-administered drugs (PADs)

CMS currently requires that states submit rebates to manufacturers for all PAD single-source drugs and the top 20 high-dollar-volume multiple-source innovator PADs. CMS is proposing to expand this requirement to apply to all PADs that meet the definition of a COD regardless of dollar volume.

In order to operationalize this requirement, state Medicaid programs will have to require providers to submit separate charges for all PADs to Medicaid beneficiaries that include the National Drug Code (NDC) of the drug. If the proposed rule is implemented, providers will have to evaluate their charging processes for PADs that meet the definition of a COD to ensure these charges are not being suppressed.

Key considerations:

- Does your facility currently identify the NDCs of all CODs on claims?

What controls does your facility have in place to ensure that the NDC submitted on the claim corresponds to the NDC actually administered when the drug is a multiple-source PAD?

Updates to Medicaid managed care benefit cards

Patients enrolled in Medicaid managed care organizations (MCOs), prepaid inpatient health plans (PIHPs) or prepaid ambulatory health plans (PAHPs) generally use identification cards at the pharmacy to obtain prescription drug benefits. These cards also allow pharmacies to process and bill claims.

Health plans use two codes on the card to identify a patient's plan: the processing bank identification number (BIN) and processor control number (PCN). This information is not always placed on Medicaid plan ID cards, making it difficult to determine at the point of sale whether a patient is a Medicaid beneficiary.

CMS proposes to require that these plans assign and exclusively use unique Medicaid BIN, PCN and group numbers that will be identified on all Medicaid plan ID cards. The purpose of this rule is to make it easier for outpatient pharmacies to identify Medicaid plans and prevent duplicate discounts.

- Has your facility been excluding managed care claims due to the challenges of isolating MCO plans under the current system?
- If the proposed rule is implemented as written, will you reevaluate that approach?
- What processes does your covered entity have in place to identify 340B drugs dispensed to patients covered by MCOs in the outpatient retail pharmacy?
- Does your organization maintain a list of Medicaid BIN/PCN/group numbers?
- What controls are in place to ensure the BIN/PCN/group list remains up to date as plans change and new plans are introduced to the market?

Government Contract Services
Ernst & Young LLP

Alexandra Mooney Bonelli
Principal
+1 212 773 4733
alexandra.mooney@ey.com

Garrett Pape
Senior Manager
+1 312 879 5791
garrett.pape@ey.com

Matt Newman
Manager
+1 202 327 5714
matthew.newman@ey.com

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