INFORMATIONAL BULLETIN FROM CMS ADDRESSES BEST PRACTICES TO AVOID 340B DUPLICATE DISCOUNTS

On January 8, 2020, the Centers for Medicare & Medicaid Services ("CMS") released an Informational Bulletin titled "Best Practices for Avoiding 340B Duplicate Discounts in Medicaid" ("Bulletin"). The Bulletin outlines best practices that CMS encourages state Medicaid agencies to consider to avoid the situation where a manufacturer provides both a Medicaid drug rebate and a discount under the 340B drug discount program ("340B Program"), commonly referred to as a "duplicate discount."

The prohibition on duplicate discounts has always been part of the 340B Program. The increasing number of Medicaid managed care beneficiaries and the volume of prescriptions filled at 340B Program covered entity ("Covered Entity") contract pharmacies, however, has made preventing duplicate discount billing progressively more difficult. Unfortunately, the size, scope and complexity of the 340B Program have prevented policymakers and the industry from finding a single workable solution to the duplicate discount problem.

The Bulletin is the latest effort by CMS and the Health Resources & Services Administration ("HRSA") to provide potential solutions and best practices for states to consider to avoid duplicate discounts. While not all of the recommended best practices are new, and the Bulletin is not legally binding, it provides insight to 340B Program stakeholders regarding CMS's 340B Program priorities and Covered Entities should assume that many state Medicaid agencies will eventually implement some or all of the recommendations.

In anticipation, Covered Entities should, at a minimum, review existing policies and operational procedures for preventing duplicate discounts and begin preparing for increased scrutiny by state Medicaid agencies, manufacturers, Medicaid managed care organizations and third-party auditors.

BACKGROUND AND THE BULLETIN

State Medicaid agencies are prohibited from billing manufacturers for Medicaid rebates for drugs dispensed to Medicaid patients that were already discounted under the 340B Program. In order to avoid claiming these duplicate discounts, state Medicaid agencies must be able to identify claims that include 340B drugs and exclude them from the utilization data submitted to drug manufacturers.

To help states determine whether a 340B drug was dispensed to a Medicaid beneficiary, HRSA established the Medicaid Exclusion File ("MEF") for Medicaid fee-for-service ("FFS"). The MEF lists Covered Entities that elected to dispense 340B-purchased drugs to Medicaid patients, along with their National Provider Identification ("NPI") numbers and Medicaid billing number. The use of the MEF to identify 340B drug claims, however, is imperfect and state Medicaid agencies are not required to use the MEF. In addition, the MEF is limited to Medicaid FFS.

State Medicaid agencies have attempted to use a variety of other mechanisms to avoid duplicate discounts. These include requiring certain modifiers on claims, using unique bank identification numbers ("BINs") and processor control numbers ("PCNs") and shifting Medicaid pharmacy benefits entirely to the Medicaid FFS system.

The Department of Health and Human Services Office of Inspector General ("OIG") issued multiple reports[1] highlighting the various state Medicaid agency oversight activities and methods and the continued risk of duplicate discounts despite these efforts. A 2017 OIG report, for instance, found that the State of Wisconsin's Department of Health Services ("DHS") failed to properly invoice manufacturers for rebates of approximately $3 million in physician-administered drugs, resulting in improper reimbursement from federal funds over three years.[2] Specifically, the report stated that the Wisconsin DHS failed to invoice manufacturer rebates on single-source drugs and top-20 multiple-source drugs.

In response to these challenges and the OIG reports encouraging CMS to show state Medicaid agencies ways to avoid duplicate discounts, CMS developed the Bulletin outlining seven regulatory strategies for state Medicaid agencies to consider when developing their own policies. The strategies are not all new. Many of the strategies, such as the use of the MEF, represent approaches that state Medicaid agencies currently use. Below is the complete list of specific strategies recommended in the Bulletin:

1. State Medicaid agencies should consider referring to the MEF to organize information about the Medicaid Drug Rebate Program ("MDRP") submissions to drug manufacturers and which Covered Entities billed for 340B drugs;
2. State Medicaid agencies should consider entering written, three-party agreements between the state Medicaid agency, a Covered Entity and its contract pharmacy to govern the retrospective identification of 340B Program claims. In such cases, the Covered Entity must submit a copy of the agreement to HRSA for inclusion in Covered Entity reports;
3. State Medicaid agencies should consider entering a state plan amendment ("SPA") to limit Covered Entities' and contract pharmacies' abilities to use 340B Program-purchased drugs to treat Medicaid beneficiaries. SPAs may help resolve situations that can result in duplicate discounts by restricting the entities that may distribute 340B drugs or requiring the reporting of certain 340B drug distribution information;
4. State Medicaid agencies should consider using 340B Program claims identifiers such as submission clarification codes, state-specific modifiers or physician-administered drug billing modifiers to prospectively identify 340B Program claims;
5. State Medicaid agencies should consider implementing processes and procedures to exclude 340B Program claims submitted to Medicaid managed care organizations from state Medicaid agency's MDRP rebate requests;
6. State Medicaid agencies should consider providing additional claims-level data to drug manufacturers that may facilitate rebate 340B Program claim identification; and
7. State Medicaid agencies should consider working with pharmacy benefit managers ("PBMs") to require Medicaid managed care organizations to use specific BIN/PCN combinations unique to Medicaid products. This would help facilitate the identification and removal of such claims from state Medicaid agency's MDRP rebate requests since states can more quickly determine whether a 340B drug was dispensed to a Medicaid beneficiary at a Covered Entity location.

PRACTICAL TAKEAWAYS

The Bulletin is not legally binding on the 340B Program or state Medicaid programs. Rather, it serves as guidance for state Medicaid agencies given their responsibility and role with respect to ensuring mechanisms that prevent duplicate discounts. It also demonstrates that CMS and manufacturers are more attuned to duplicate discounts in the Medicaid managed care space. As a result, 340B and Medicaid managed care contracting staff should be aware of the potential for increased scrutiny regarding Medicaid managed care plans and 340B Program duplicate discounts.

Adopting certain proposed strategies could significantly impact Covered Entities and contract pharmacies, as well as the corresponding 340B Program savings realized. Of particular concern to Covered Entities, for instance, is language in the Bulletin stating that state Medicaid agencies could "limit the ability of some or all of the covered entities and/or contract pharmacies in the state to use 340B-purchased drugs for Medicaid beneficiaries" via the SPA process.

Since the implications could extend to Medicaid managed care plans, Covered Entity and contract pharmacy advocacy team members should be aware of this focus and should look for opportunities to work with state Medicaid agencies in evaluating whether to adopt one or more of these proposed strategies.

If you have any questions or would like additional information about this topic, please contact:

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[references]

[1] *See* https://oig.hhs.gov/oei/reports/oei-05-09-00321.pdf and https://oig.hhs.gov/oei/reports/oei-05-14-00430.pdf.

[2] https://oig.hhs.gov/oas/reports/region5/51600014.pdf.

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