A FLURRY OF RECENT ACTIVITY HIGHLIGHTS CONTINUED INTEREST IN 340B PROGRAM OVERSIGHT

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Four separate government releases coming over a three-week period have once again highlighted the intense interest in the 340B drug pricing program, with a federal agency and two government watchdog groups issuing guidance and findings related to 340B.

- On January 8, 2020, the Centers for Medicare and Medicaid Services (CMS) issued an informational bulletin outlining its view on "best practices" for states to prevent 340B duplicate discounts in Medicaid.

- On January 10, 2020, the Government Accountability Office (GAO) publicly released a report making recommendations to the Health Resources and Services Administration (HRSA) for increased oversight of non-profit hospitals' participation in 340B.

- On January 17, 2020, the Medicare Payment and Advisory Commission (MedPAC) discussed preliminary findings in a study of Medicare spending on cancer drugs in 340B hospitals compared to other providers.

- On January 27, 2020, GAO publicly released a report making recommendations to CMS and HRSA for increased oversight of states and 340B providers related to the prevention of 340B duplicate discounts in Medicaid.

Collectively, the recent activity highlights continued interest in oversight of providers in the 340B program and the possibility of a tightening of compliance standards, particularly for non-profit hospitals. 340B providers should be prepared for possible changes in guidance from states and through HRSA audit enforcement as a result of the CMS and GAO actions. In particular, non-profit hospitals should review the documentation they rely on to support eligibility to participate in the 340B program, in light of the GAO report.

GAO Report and CMS Informational Bulletin on 340B Duplicate Discounts in Medicaid

GAO issued a report on January 21, 2020, publicly released on January 27, 2020, evaluating activity by states and the Department of Health and Human Services (HHS) to prevent 340B duplicate discounts in Medicaid. A duplicate discount occurs when a drug manufacturer provides a 340B discount to a provider and pays a rebate to a state Medicaid agency on the same drug.

The report, requested by four Republican members of Congress, follows a 2016 HHS Office of the Inspector General (OIG) report that recommended CMS require states to implement mechanisms to identify 340B claims billed to Medicaid managed care and that HRSA issue guidance on the prevention of...
Medicaid managed care duplicate discounts. A 2018 report from the GAO also recommended HRSA increase oversight of 340B duplicate discounts in Medicaid managed care.

GAO's latest report includes a review of state policies on use and identification of 340B drugs. GAO found that state policies vary and are not always documented, leading GAO to conclude that state policies may not always prevent duplicate discounts. GAO also reviewed HHS oversight and found that CMS does not track or review state policies to prevent duplicate discounts. GAO found that, as part of HRSA audits, the agency does not independently verify whether providers are following state policies, and HRSA does not require providers to repay manufacturers when instances of duplicate discounts in Medicaid managed care are identified.

GAO recommended that CMS ensure states have written policies and procedures regarding the use and identification of 340B drugs and that HRSA assess compliance with state policies in audits and require providers to repay manufacturers when instances of Medicaid managed care duplicate discounts are identified. HHS concurred with the recommendation for CMS and did not concur with the recommendations directed to HRSA, citing, in part, a lack of authority.

The GAO report follows an informational bulletin issued by CMS on January 8, 2020, which outlined best practices for how states can avoid duplicate discounts in 340B and Medicaid. Several of the best practices highlight mechanisms that states commonly use to identify 340B claims and exclude them from rebate collection, including requirements for providers to attach modifiers to claims for 340B drugs. However, one of the so-called "best practices" suggests that states could prohibit 340B providers from using 340B drugs for Medicaid patients to prevent duplicate discounts.

Implications

In light of the GAO report and CMS' informational bulletin, providers should monitor state guidance for changes to 340B billing expectations. In response to the CMS bulletin, it is possible that states may consider revising their current guidance on how 340B providers should prevent duplicate discounts and could prohibit covered entities and contract pharmacies from billing Medicaid for 340B drugs. Such changes in state policy could limit how much providers can access through 340B savings.

Potential next steps by HRSA are less clear. The agency previously concurred with GAO's 2018 recommendation that HRSA issue guidance on the prevention of duplicate discounts under Medicaid managed care. According to GAO, HRSA is "working to determine next steps to address these recommendations." However, hospitals have called into question HRSA's authority to issue guidance in this area, arguing that the 340B statute does not obligate providers to prevent Medicaid managed care duplicate discounts, as managed care duplicate discounts are prohibited under the Medicaid statute, not 340B.

**GAO Report on Non-Profit Hospital Eligibility for 340B**

In response to a request by four Republican members of Congress, the GAO reviewed contracts between hospitals and state and local government that qualify non-profit hospitals for the 340B program. The requesters asked GAO to provide information on such contracts, given growth in the number of hospitals in the 340B program. The GAO issued a report on December 11, 2019, publicly released on January 10, 2020, titled, "340B Drug Discount Program: Increased Oversight Needed to Ensure Nongovernmental Hospitals Meet Eligibility Requirements."

To participate in 340B, hospitals must either be owned or operated by a unit of state or local government, formally granted governmental powers, or a private non-profit hospital that has a contract with state or local government to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid. GAO found that, as of January 1, 2019, nearly 1,700 of the roughly 2,500 hospitals in 340B – more than two-thirds – were private non-profit hospitals, referred to as "nongovernmental hospitals."
GAO reviewed contract documentation for 258 nongovernmental hospitals and identified "weaknesses" in how HRSA reviews nongovernmental hospital contracts. GAO concluded that "some nongovernmental hospitals that do not appear to meet the statutory requirements for program eligibility are participating in the 340B Program and receiving discounted prices for drugs for which they may not be eligible."

GAO found that the contract documentation appeared to meet the statutory requirements for the vast majority of hospitals in the review. On the other hand, some of the documents reviewed did not appear to be "contracts," based on GAO's "common" definition of contracts, and a small number of contracts did not appear to require hospitals to provide health care services to the requisite low-income population. GAO made six recommendations to HRSA for increased oversight of nongovernmental hospitals' participation in 340B, including calls for HRSA to verify that nongovernmental hospitals have contracts in place that meet the statutory requirements and update audit enforcement standards accordingly.

In response, HRSA noted that the agency is "currently evaluating its audit process and other program integrity efforts as they relate to HRSA's ability to enforce and require corrective action in a Program that is primarily administered by guidance." Importantly, HRSA stated that the agency "is not pursuing new guidance under the Program at this time."

HRSA, as part of future registrations, plans to require that hospitals provide copies of contracts to HRSA. In addition, HRSA concurred with GAO's recommendation that the agency amend its contract integrity check procedures to include review of whether the contracts require the provision of health care services to low-income individuals who are not eligible for Medicare or Medicaid. HRSA said it is reviewing its internal procedures to determine feasibility of including a review of whether contracts include this element.

HRSA's response also sheds light on the agency's latest audit procedures. HRSA said it instructs its auditors to contact HRSA if certain elements are not easily identified in a hospital's contract or are "questionable in nature."

**Implications**

Non-profit hospitals should be prepared for a potential tightening of HRSA's audit standards and compliance expectations regarding the elements that should be included in non-profit hospital contracts with state and local government. Non-profit hospitals should review the contract documentation they maintain to support 340B eligibility to ensure it is consistent with HRSA's expectations.

**MedPAC Preliminary Findings on Medicare Spending in 340B Hospitals**

During a public meeting held January 17, 2020, MedPAC staff presented preliminary results of an analysis of Medicare drug spending for cancer in 340B hospitals compared to non-340B providers. MedPAC evaluated whether the 340B program creates incentives for hospitals to use more expensive drugs, in response to a Congressional request in August 2018.

MedPAC focused on five types of cancer and found higher spending in 340B hospitals for two of the five (lung and prostate) but was "unable to attribute these findings to incentives created by 340B discounts." A prior GAO study suggested that higher spending in 340B hospitals may be the result of 340B hospitals using more drugs or more expensive drugs.

CMS has cited the GAO's findings in support of the reduced Medicare Part B drug reimbursement rates to 340B hospitals that went into effect in 2018. Proponents of the payment cuts have suggested they would diminish any incentives inherent in 340B for hospitals to use more drugs or more expensive drugs. MedPAC analyzed pre-2018 data from before the Medicare payment cuts went into effect.

MedPAC is expected to include the 340B analysis in the commission's March 2020 report to Congress.

**Implications**
As hospitals continue to challenge Medicare's authority to reduce payment to 340B hospitals, with litigation pending in the D.C. Circuit Court of Appeals, hospitals may be able to rely on MedPAC's new findings to undercut part of CMS's policy rationale for reduced payment rates. The Court is evaluating whether the payment reduction implemented in 2018 and continued in 2019 exceeded CMS's authority under the Medicare statute. Oral arguments were held in November 2019, and hospitals are awaiting a decision. Meanwhile, the payment reduction continues to be in effect in 2020.

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