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2020 Starts Off With Two Government Publications Critical Of 340B Program Oversight

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Less than two weeks into the new year, the federal government has released two new publications addressing concerns related to 340B Program oversight by both state and federal agencies. After a relatively quiet 2019, 340B Covered Entities should be prepared for increased scrutiny, oversight and the potential for additional 340B Program compliance requirements in 2020.

IN DEPTH

After a comparatively quiet 2019, 340B Covered Entities should be prepared for increased scrutiny, oversight and the potential for additional 340B Program compliance requirements in 2020. Less than two weeks into the new year, the federal government has released two new publications addressing concerns related to 340B Program oversight by both state and federal agencies.

On January 8, 2020, the Centers for Medicare and Medicaid Services (CMS) issued an "Informational Bulletin" to state Medicaid programs on *Best Practices for Avoiding 340B Duplicate Discounts in Medicaid*. This publication was followed on January 10, 2020, by the release of a long-awaited Government Accountability Office report on oversight of non-governmental hospitals participating in the 340B Program by the Health Resources and Services Administration (HRSA).

Based on the information provided in these two publications, we expect to see additional obligations being imposed on 340B Covered Entities by both state Medicaid agencies and HRSA in the coming months, particularly as they relate to limitations on dispensing of 340B drugs to Medicaid Managed Care plan enrollees and 340B nongovernmental hospitals' contracts with state and location governments. In anticipation of such additional obligations and oversight relating to duplicate discount prevention all Covered Entities should consider reviewing the effectiveness of their duplicate discount prevention policies, procedures, and operations and nongovernmental hospitals should also evaluate contracts with state and local governments supporting 340B Program eligibility for consistency with 340B statutory requirements.

CMS Informational Bulletin on Best Practices for Avoiding 340B Duplicate Discounts

State Medicaid agencies are prohibited from billing manufacturers for Medicaid rebates for drugs dispensed to Medicaid patients that have already been discounted under the 340B Program. If a manufacturer erroneously provides both a discount and a rebate on a drug, it is considered a “duplicate discount” and the 340B Covered Entity that dispensed and billed Medicaid for the drug may be subject to repayment of the 340B discount to the manufacturer.

Identification of 340B drugs dispensed to Medicaid beneficiaries for purposes of preventing duplicate discounts has been challenging for state Medicaid agencies, 340B Covered Entities, and drug manufacturers. States have experimented with a variety of methods to attempt to identify 340B drugs dispensed to Medicaid beneficiaries, but neither CMS nor HRSA have issued regulations requiring specific duplicate discount prevention processes by 340B Covered Entities or state Medicaid agencies. The identification and prevention of duplicate discounts is further complicated when 340B drugs are dispensed through contract pharmacy arrangements or paid by Medicaid Managed Care plans, as such arrangements create additional barriers to and parties involved with transmission of 340B purchasing information from Covered Entities to the State.

Recognizing the challenges that states have in identifying Medicaid claims for 340B drugs, but stopping short of requiring any specific methodology for states to identify the claims, CMS released an Informational Bulletin to state Medicaid programs that lists and explains seven different approaches, which CMS describes as “best practices”, that states could adopt to avoid duplicate discounts. The seven approaches are summarized below in Table 1.

Table 1

CMS Best Practice to Avoid Duplicate Discounts	Analysis
Use the 340B Medicaid Exclusion File (MEF) to identify 340B Covered Entities that dispense 340B drugs to Medicaid beneficiaries.	CMS notes that the MEF does not apply to arrangements between Covered Entities and Medicaid Managed Care plans and, therefore, can be used only to identify Medicaid Fee-For-Service (FFS) claims.
Develop strategies with Contract Pharmacies.	CMS notes that 340B Covered Entities are not permitted to dispense 340B drugs to Medicaid FFS beneficiaries through contract pharmacy arrangements unless they have received approval from HRSA and provide a link to the website where states can view a list of Covered Entities that have received such approval.
Limit Medicaid reimbursement for 340B Drugs purchased by Covered Entities.	CMS notes that states can utilize the State Plan Amendment (SPA) process to receive approval to place parameters around the ability of Covered Entities and contract pharmacies to dispense 340B drugs to Medicaid FFS beneficiaries, as well as to require Covered Entities to notify the state of 340B dispensing to Medicaid beneficiaries. As an example, CMS includes use of SPAs to limit the ability of Covered Entities to dispense 340B drugs

	to Medicaid beneficiaries and require Covered Entities to use non-340B drugs for Medicaid beneficiaries. The Informational Bulletin does not address the impact that such Medicaid dispensing restrictions may have on Covered Entities subject to the 340B GPO Prohibition and could incur significantly higher drug costs if restrictions are placed on dispensing 340B drugs to Medicaid beneficiaries.
Use 340B claims identifier options.	CMS identifies and provides descriptions of five separate codes that can be placed on claims for 340B drugs, including pharmacy claim identifiers “20” and “08”, as well as hospital claim identifiers “UB,” “JG,” and “TB.” Of particular interest to 340B Covered Entities, CMS indicates that code “20” is expected to be discontinued in the future and suggests to state Medicaid agencies that they use the “JG” and “TB” modifiers to identify (and exclude from rebate requests) 340B claims, including through instructions to Medicaid Managed Care plans to use these modifiers to identify claims to exclude from utilization data submitted to the state.
Include 340B duplicate discount provisions in Medicaid managed care contracts.	CMS uses the Informational Bulletin to remind states that they are required to comply with the provisions of 42 CFR § 438.3(s)(3), which obligate states to include provisions in Medicaid managed care contracts that instruct the Medicaid managed care plans to exclude utilization data for drugs subject to 340B discounts, unless the state requires submission of Medicaid managed care drug claims data directly from the Covered Entities.
Provide claims-level data to manufacturers.	CMS suggests that states could provide Medicaid drug claim data directly to manufacturers to assist in identifying duplicate discounts, although CMS recognizes that providing such data is not required. CMS notes, however, that it believes that providing such data could reduce administrative burdens and costs to the states in identifying and validating duplicate discount data.
Use specific Medicaid BIN/PCN on Medicaid managed care plan identification cards.	Recognizing that contract pharmacy claims create particular problems for duplicate discount prevention, CMS recommends that states require Medicaid managed care plans and their Pharmacy Benefit Managers to use Medicaid-specific BIN/PCN numbers. Currently, some plans use the same BIN/PCN for Medicaid and non-Medicaid enrollees, making it difficult to identify Medicaid pharmacy claims. If claims cannot be identified as

	Medicaid claims, it complicates management of duplicate discount prevention approaches. CMS acknowledges that once a claim is identified as a Medicaid claim, additional data is required to determine if the claim relates to a 340B-purchased drug.

The release of the Informational Bulletin suggests that CMS is continuing to monitor state efforts to reduce duplicate discounts and could begin to take enforcement action against states that do not comply with regulatory requirements related to duplicate discount prevention, including those related to Medicaid managed care plan contracts. 340B Covered Entities should be prepared for increased state regulation of 340B Medicaid claims and dispensing, as well as increased restrictions on use of 340B drugs under Medicaid managed care plan arrangements.

GAO Report on HRSA Oversight of Nongovernmental Hospital Eligibility Requirements

Hospitals participating in the 340B Program must be either governmental hospitals or nonprofit hospitals. Nonprofit hospitals that participate in the 340B Program are required to contract with state or local governments to provide healthcare services to low-income individuals not eligible for Medicare or Medicaid. In response to a request from the Republican leadership of the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce arising out of concerns about growth in nongovernmental hospital participation in the 340B Program, the Government Accountability Office (GAO) recently conducted a review of HRSA's oversight of compliance of nongovernmental hospitals with the nonprofit status and government contract requirements.

GAO concluded in a report released publicly on January 10, 2020, that HRSA's oversight of both the nonprofit status requirements and government contract requirement is lacking, primarily due to HRSA's reliance on self-attestations of compliance, as well as limited and inconsistent review of verifiable primary-source documentation. GAO recommended six specific actions for HRSA to take to increase its oversight of nongovernmental hospital eligibility requirements. The Department of Health and Human Services (HHS) concurred with GAO on all but one of the recommendations, although HHS also noted that HRSA would be most effectively able to oversee the 340B Program if it were granted regulatory authority to do so by Congress, consistent with the request in the FY 2020 President's Budget. A list of the recommendations is provided below in Table 2.

Table 2

GAO Recommendation	**Analysis**
HRSA should ensure that information used to verify nonprofit status is reliable.	GAO found that HRSA relies primarily on CMS Medicare Cost Report data to verify hospitals' government or nonprofit status, but that HRSA did not validate that the CMS data is accurate or consistent with 340B Program nonprofit requirements. HRSA indicated that it may request submission of supporting documentation (*e.g.*, IRS form 990, IRS letter, state letter) and that such documentation must be a part of a nongovernmental hospital's auditable records and available on request at any time.

HRSA should implement a process to verify that every nongovernmental hospital that participates in the 340B Program has a contract with state or local government.	GAO found that HRSA does not adequately verify the existence of a contract with state or local government for all nongovernmental hospitals and instead relies on hospitals' self-certification that such contracts exist. Notably, HHS did not agree that HRSA should implement a process to verify the existence of a contract for every nongovernmental hospital because HHS does not believe HRSA has the resources to do so and that such a process would create significant burdens for hospitals.
HRSA should amend its contract integrity check procedures to review whether government contracts require the provision of healthcare services to low-income individuals not eligible for Medicare or Medicaid.	GAO found that certain contracts it reviewed in the course of its review did not include requirements for the contracting hospital to provide healthcare services to low income individuals not eligible for Medicare or Medicaid, or did not state how such compliance would be determined or evaluated. HHS is concerned with this recommendation and noted that HRSA is evaluating the feasibility of incorporating additional review of contracts into its internal procedures, although HRSA indicted that such reviews have not previously occurred due to resource constraints. HRSA noted that the 340B statute does not specify what types of services are required to be provided.
HRSA should provide guidance to audit staff on how to review government contracts for compliance with 340B statutory requirements.	GAO found that HRSA had not provided adequate or consistent instruction to auditors on how to determine whether contracts included requirements to provide healthcare services to low-income individuals not eligible for Medicare or Medicaid. HHS concurred with this recommendation and indicated that HRSA had already updated its standard operating procedures for auditors to include instructions to notify HRSA if an auditor has any concerns with a contract or the required elements are not easily identifiable in the contract.
HRSA should revise audit procedures to require auditors to document review and assessment of whether government contracts are appropriately signed, cover the period under review, and require provision of healthcare services to low-income individuals not eligible for Medicare and Medicaid.	GAO found that HRSA auditors did not routinely document their affirmative review and assessment of the required government contract elements. HHS agreed with this recommendation and indicated that HRSA had already updated its audit procedures to comply with this recommendation.
HRSA should require nongovernment hospitals to demonstrate that they have government contracts in place prior to the beginning of the auditor's review period and should apply consistent and appropriate consequences for hospitals that are unable to do so.	GAO found that HRSA auditors were permitting hospitals to retroactively enter into government contracts if the hospitals were unable to produce valid contracts during an audit. HHS concurred with GAO's recommendation and noted that HRSA included additional requests for contract information in the Information Collection Request

	that it submitted to the Office of Management and Budget and for public comment in fall 2019. HHS further noted, however, that the 340B Statute does not provide HRSA with the authority over the specific contract details, resulting in enforcement actions being evaluated on a case-by-case basis.

In light of HHS' agreement with GAO's recommendations, we expect nongovernmental 340B hospitals to see significantly increased scrutiny and oversight of their compliance with nonprofit status and government contract requirements in the coming year. We have already seen some evidence of additional scrutiny in requests from HRSA for government contract information from currently enrolled nongovernmental hospitals.

Nongovernmental hospitals participating in the 340B Program should review their existing contracts used for 340B eligibility purposes to ensure they meet state law contract requirements and comply with 340B Program statutory requirements.

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