Health Care Alert: Top Changes to Watch For in the 340B Drug Discount Program

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For many providers, the 340B program – which requires pharmaceutical manufacturers to provide covered outpatient drugs to certain eligible hospitals and federal grantees at discounted prices in order to have their drugs covered under Medicaid – is a crucial source of revenue that supports much-needed and otherwise uncompensated charity care.

In recent years, however, the rapid growth of the program has prompted concern that it is no longer serving its intended purpose, in turn leading to widespread criticism and discussion of reform. The first significant shift occurred in November 2017, when the Centers for Medicare and Medicaid Services (CMS) published a final rule reducing the reimbursement amount for 340B drugs under Medicare Part B from average sales price (ASP) plus 6% to ASP minus 22.5%. But the changes are unlikely to stop there: in June 2018, the Government Accountability Office (GAO) released a report critiquing federal oversight of contract pharmacy arrangements under 340B and recommending 7 specific actions by the program's administrating agency, the Health Resources and Services Administration (HRSA). On July 11, the Health Subcommittee of the House Committee on Energy and Commerce held a hearing to discuss potential reforms, including 15 separate bills and discussion drafts already under consideration.

Although it remains unclear exactly what will come of these discussions, here are the top three changes 340B providers should watch for:

Updates to the definition of a "patient."

Federal regulations implementing the 340B program prohibit the "diversion" of drugs purchased under program discounts, including the provision of such drugs to individuals who are not "patients" of the 340B-eligible entity. However, neither the program's authorizing statute nor the implementing regulations define the term "patient," and the definition currently used comes from guidance issued by HRSA in 1996.[1]

Although at least one current House bill (the Stretching Entity Resources for Vulnerable Communities or SERV Act) proposes codifying the current patient definition,[2] several witnesses before the Subcommittee testified that narrowing the patient definition would help to prevent inappropriate utilization of the program. New York Representative Chris Collins suggested that uninsured or low-income status be incorporated into the patient definition, which would eliminate providers' ability to generate revenue by supplying 340B-discounted drugs to insured patients and redirecting the savings into other initiatives. While it is likely that the final definition will be less narrow, providers may expect to see new guidance in this area as HRSA and legislators work to clarify the intent and scope of the 340B program.

Increased reporting requirements with respect to program revenue and arrangements with contract pharmacies.

As noted above, 340B providers are currently able to generate revenue by supplying 340B-discounted drugs to fully-insured patients; however, in the absence of any requirements for providers to report how such revenue is used, there is no way to verify that the savings are being used to benefit those the program was intended to serve.

Critics of the 340B program have cited a pervasive lack of transparency and accountability for participating providers, and any reforms are likely to include new requirements to track and disclose the use of 340B savings.

Additionally, the GAO specifically recommended that HRSA begin requiring program participants to register their contract pharmacies in order to improve program integrity. Notably, the number of pharmacies with which an entity contracts is among the criteria HRSA considers in identifying the targets of its risk-based audits,[3] which – historically relatively infrequent[4] – are likely to increase in light of Congressional scrutiny.

Increased scrutiny of compliance with the prohibition on duplicate discounts, particularly under Medicaid managed care.

Another key prohibition of the 340B program forbids "duplicate discounts," which result when a provider improperly receives a Medicaid drug rebate for a drug on which it has already received a 340B discount.

Dr. Debra Draper of the GAO testified that there is currently no mechanism to track and prevent duplicate discounts under Medicaid managed care, and that this vulnerability will be the subject of an upcoming GAO report. While this project is still in its early stages, providers should note that improper duplicate discounts could result in an overpayment of Medicaid funds, which in turn may give rise to an obligation under the False Claims Act (FCA). The applicable lookback period for Medicaid overpayments depends on state law, but typically extends five to six years - thus, it is important that providers have their own mechanisms in place now to ensure compliance.

Please feel free to contact us with any questions as the Vorys health care industry team continues to monitor developments in the 340B program. Also, watch for our upcoming webinar series on Medicare and Medicaid overpayments to make sure that your organization is prepared and protected.

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[1] *See* 61 F.R. 55156, *Notice Regarding Section 602 of the Veterans' Health Care Act of 1992 Patient and Entity Eligibility*, Oct. 1996. Available at: https://www.gpo.gov/fdsys/granule/FR-1996-10-24/96-27344.

[2] H.R. 6071, 115th Cong. (2018).

[3]*See* Government Accountability Office, *Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement*, Jun. 2018, p. 15. Available at: https://www.gao.gov/assets/700/692697.pdf. Other criteria include volume of 340B drug purchases, time in the 340B program, complexity of the entity's program, and history of violations or allegations of noncompliance associated with diversion and duplicate discounts.

[4] *Id*. The GAO's report found that HRSA audited only 1.6% of covered entities in 2017, up from 0.5% in 2012.