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To Be or Not to 340B: HHS Issues Advisory Opinion and New GAO Report Sheds Light on HRSA's Enforcement Pullback

By Brenda M. Maloney Shafer, Richard B. Davis, and David M. Blank*

Many drug manufacturers have decided that the Health Resources and Services Administration's Office of Pharmacy Affairs guidance on contract pharmacy arrangements is no longer binding. Accordingly, some have curtailed selling 340B-priced drugs based on contract pharmacy encounters, causing a significant disruption in operations and loss in revenue for all types of 340B covered entities. The authors of this article discuss the issue and an advisory opinion stating that the law requires manufacturers to offer 340B pricing on appropriate drugs dispensed by contract pharmacies.

2020 was a tumultuous year for virtually everyone and everything, and the 340B Program was no exception. Many drug manufacturers have decided that the Health Resources and Services Administration's Office of Pharmacy Affairs ("HRSA OPA") guidance on contract pharmacy[1] arrangements is no longer binding. Accordingly, many drug manufacturers have curtailed selling 340B-priced drugs based on contract pharmacy encounters, causing a significant disruption in operations and loss in revenue for all types of 340B covered entities. Finally, in keeping with the "roller coaster" nature of the year, the Department of Health and Human Services ("HHS"), the agency that generally oversees HRSA OPA, issued an advisory opinion on December 30, 2020[2] (the "Advisory Opinion") stating the law requires manufacturers offer 340B pricing on appropriate drugs dispensed by contract pharmacies.

BRIEF BACKGROUND LEADING TO THE ADVISORY OPINION

By way of brief background, here is the mile-high summary and timeline of the issue:

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[1] Based on existing HRSA OPA guidance (the validity of which is now in question), a 340B covered entity may contract with third-party pharmacies to dispense 340B drugs on the covered entity's behalf.

[2] https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/340B-AO-FINAL-12-30-2020_0.pdf.

The statute governing the 340B Program is very sparse, and does not directly address various program elements, such as contract pharmacy arrangements or the eligible patient definition.

- Traditionally, HRSA OPA has filled in the gaps via the issuance of "guidance" documents published in the Federal Register and on its website. While HRSA OPA attempted to promulgate formal and comprehensive rules over the years, the courts roundly rejected these attempts, declaring that HRSA OPA did not have such comprehensive rulemaking authority.
- Until recently, the 340B Program stakeholders generally abided by these guidance documents. Over the past year, however, HRSA OPA seemingly reevaluated its enforcement authority, claiming it only has authority to regulate those areas of the 340B Program directly covered by the statute.[3]
- Due to this pullback by HRSA OPA of its enforcement authority, drug manufacturers decided that they would eliminate or severely curtail their sale of 340B priced drugs based on contract pharmacy dispensing.
- Various 340B covered entities have filed lawsuits against HHS asking HHS to enforce the existing contract pharmacy guidance. Alternatively, the 340B covered entities are seeking clarification from HHS on the legal status of the 340B guidance so they can react with some certainty moving forward.
- On September 21, 2020, HHS took the highly unusual step of publishing its response to a manufacturer's request for a pre-enforcement advisory opinion as to whether the manufacturer's actions could subject the manufacturer to sanctions. In this response, HHS indicated that, while it "has significant initial concerns" with the manufacturer's new policy, it "has yet to make a final determination as to any potential action." Nonetheless, HHS did indicate that HRSA's silence on the issue (particularly in light of the pandemic), should not be viewed as acquiescence and threatened potential false claim actions for knowing violations of 340B Program requirements.
- Despite this strongly worded response from HHS, the manufacturers

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[3] "HRSA explained that its 'current authority to enforce certain 340B policies contained in guidance is limited unless there is a clear violation of the 340B statute,' and that '[w]ithout comprehensive regulatory authority, HRSA is unable to develop enforceable policy that ensures clarity in program requirements across all the interdependent aspects of the 340B Program.' " Complaint at 17.

continued to curtail their sales of 340B-priced drugs dispensed via contract pharmacy arrangements.

- Finally, on December 30, 2020, HHS issued its Advisory Opinion indicating that manufacturers are required to sell eligible drugs at 340B prices to covered entities "even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."

THE ADVISORY OPINION

At its core, the "Advisory Opinion sets forth the current views of the Office of the General Counsel [of HHS]. It is not a final agency action or a final order, and it does not have the force or effect of law."

Nonetheless, the Advisory Opinion lays out the key legal arguments supporting the permissibility of contract pharmacy arrangements. These arguments are (very briefly) summarized as follows:

- The plain language of the 340B statute requires merely that the 340B-eligible drug "be purchased by" the covered entity. Colorfully, the Advisory Opinion clarifies that so long as the covered entity "purchases" the drug, the "situs of delivery, be it the lunar surface, low-earth orbit, or a neighborhood pharmacy, is irrelevant."
- HRSA OPA's longstanding interpretation of the 340B Statute, as expressed through guidance, is that manufacturers are required to offer ceiling prices even where contract pharmacies are used. As HRSA OPA's guidance has been in effect for decades, and the parties have typically honored contract pharmacy arrangements until now, HRSA OPA's guidance is entitled to deference.
- If the manufacturers believe that the usage of contract pharmacies leads to potential diversion or duplicate discounts, the manufacturers have existing statutory remedies to resolve those concerns.

SO, WHAT'S NEXT?

The next steps will depend largely on the manufacturers' response to the Advisory Opinion.

At the highest level, if a manufacturer continues to curtail 340B-priced sales based on pharmacy encounters, HHS will have the option to impose a civil monetary penalty "not to exceed $5,000 for each instance of overcharging a covered entity."[4] In order to be subject to such a penalty, the overcharge must occur "knowingly and intentionally." Any civil monetary penalty assessed will

[4] https://www.govinfo.gov/content/pkg/FR-2017-01-05/pdf/2016-31935.pdf (42 C.F.R. § 10.11).

be in addition to repayment for an instance of overcharging. The manufacturers would likely argue that any failures to provide 340B-priced drugs for contract pharmacy encounters prior to the Advisory Opinion were not "knowing and intentional" because the manufacturer "acted on a reasonable interpretation of agency guidance." While the merits of this argument are far from ironclad, this argument would be quite the uphill battle for overcharges occurring after the issuance of the Advisory Opinion. Nonetheless, in the event HHS does impose penalties on the manufacturer, the manufacturer will likely sue HHS claiming that HHS exceeded its statutory authority in this specific area.

Alternatively, the manufacturers may opt to stand down and resume "pre-2020" operations. The main question in this scenario is whether HHS pursues penalties and/or requires repayment prior to the issuance of the Advisory Opinion. While the proposed approach is not clear from the Advisory Opinion, from a practical perspective, it is worth noting that 27 State Attorneys General sent a letter in support of covered entities lawsuit to uphold contract pharmacy arrangement. One of these Attorneys General was then-California Attorney General Xavier Becerra, who now leads HHS. Mr. Becerra has issued the following statement in support of the lawsuit: "Discounts afforded under the 340B Drug Pricing Program are more critical now than ever. We call on HHS to hold these non-compliant drug manufacturers accountable and provide immediate relief for healthcare centers and the Americans they serve."[5] Given this position, it is possible HHS may seek retroactive repayment under a new administration.

Of course, the manufacturers may also elect to file a preemptive challenge to this Advisory Opinion and attempt to head off the potential for enforcement. While the viability of this argument is uncertain, it is nonetheless something to monitor as stakeholders digest the Advisory Opinion.

In any event, 340B stakeholders will no doubt continue to monitor this fast-moving issue as the impact of the Advisory Opinion becomes clear, and the new administration begins to set its priorities.

GAO REPORT PROVIDES INSIGHT INTO HRSA OPA'S POSITION

One of the most frustrating aspects of HRSA OPA's apparent enforcement pullback (before the Advisory Opinion at least) is that HRSA OPA never explicitly published a statement explaining the scope and implications of such a pullback. However, a new report[6] published by the Government Account-

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[5] https://www.fiercehealthcare.com/hospitals/27-states-and-d-c-call-for-hhs-to-rein-drug-makers-over-340b-moves-after-hospital-group.

[6] https://www.gao.gov/assets/720/711209.pdf.

ability Office ("GAO") provides some insight into HRSA OPA's positions on specific 340B Program issues.

Some of the more interesting language follows:

- "HRSA officials told us [GAO] that, beginning in fall 2019, the agency started issuing findings, which require covered entities to take corrective action, only when audit information presents a clear and direct violation of the requirements outlined in the 340B Program statute. HRSA officials explained that 340B Program guidance, which is used to interpret provisions of the 340B statute for the purposes of promoting program compliance among covered entities, does not provide the agency with appropriate enforcement capability. Following a covered entity's 2019 legal challenge to HRSA's authority to enforce audit findings, HRSA evaluated its ability to require and enforce corrective action, and it concluded that in the absence of binding and enforceable regulations, the agency would no longer issue findings based solely on noncompliance with guidance."
- "For example, HRSA officials reported that there were instances among fiscal year 2019 audits in which the agency:
    - Did not issue diversion findings for dispensing 340B drugs to ineligible individuals as defined by HRSA guidance because the 340B statute does not provide criteria for determining patient eligibility; and
    - Did not issue eligibility findings for a failure to oversee 340B Program compliance at contract pharmacies through internal audits and other measures as set forth in guidance because the 340B statute does not address contract pharmacy use."
- "HRSA officials also said that there were instances among fiscal year 2019 audits in which the agency also did not issue duplicate discount findings for a failure to follow a state's Medicaid requirements, including billing the state Medicaid office for a 340B drug without using a claim identifier to indicate a drug purchased at the 340B discounted price. HRSA officials said that these findings were not issued because the agency does not have statutory authority to enforce state Medicaid requirements."

The GAO report also provides a detailed crosswalk outlining HRSA OPA's positions on more granular aspects of 340B compliance in Appendix I.

While it is helpful to see HRSA OPA's position published on a government document, we note that HRSA OPA has not been consistent in applying its

new interpretation regarding 340B Program enforcement. For example, we have worked with covered entities undergoing audits in January 2020 in which the HRSA auditors extensively relied on HRSA guidance to issue findings related to contract pharmacy arrangements and eligible patient standards—neither of which are explicitly addressed in the statute.

Lastly, despite these statements by HRSA OPA, HHS seemingly defended the validity of the guidance documents in the Advisory Opinion. It remains to be seen whether HRSA OPA will return to its former enforcement position regarding the guidance documents based on the Advisory Opinion.

CONCLUSION

In sum, 2020 did not spare the 340B Program from its general upheaval. Stakeholders will no doubt want to monitor closely the manufacturers' response to the Advisory Opinion and potential enforcement actions by HHS.