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Examining Oversight Reports on the 340B Drug Pricing Program

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Good morning, Chairman Alexander, Ranking Member Murray, and Members of the Committee. I am Ann Maxwell, Assistant Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services. I appreciate the opportunity to appear before you to discuss ways to protect the integrity of the 340B Drug Pricing Program (340B program).

OIG reviews have explored various aspects of the 340B program, identified potential vulnerabilities, and offered several recommendations to promote program integrity. Some of the weaknesses we have identified have been addressed through legislation or by the Health Resources and Services Administration (HRSA) directly. However, two long-standing, fundamental vulnerabilities persist, impeding effective program operations and oversight. Specifically, OIG work has identified: (1) a lack of transparency that prevents ensuring that 340B providers are not overpaying pharmaceutical manufacturers and that State Medicaid programs are not overpaying 340B providers; and (2) a lack of clarity regarding program rules that creates uncertainty, resulting in inconsistent program implementation and limited accountability. HRSA has taken some steps toward addressing these concerns, but it has not fully addressed either. My testimony today focuses on the two key improvements OIG recommends to support effective oversight and strengthen the integrity of the 340B program.

OIG Recommends Key Improvements to 340B Program Integrity and Oversight:

- **increase transparency to allow payment accuracy, and**
- **clarify rules to ensure that the program operates as intended.**

The 340B Program Requires Drug Manufacturers to Sell Products at Discounted Prices to Certain Safety-Net Health Care Providers

In 1992, Congress established the 340B program to generate savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at discounted prices.[1] A House report, accompanying the original legislation, stated that these savings would "enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[2] HRSA, which manages the 340B program, reported that total 340B sales in 2016 amounted to approximately $16 billion, or about 3.6 percent of the U.S. drug market.[3]

[1] Section 340B of the Public Health Service Act, 42 U.S.C. § 256b.
[2] H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).
[3] HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, p. 255. Other stakeholders have produced varying alternative estimates of the size of the 340B program relative to the broader pharmaceutical market.

Pursuant to the Public Health Service Act, drug manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge 340B providers at or below specified maximum prices, known as ceiling prices. The manufacturers calculate 340B ceiling prices each quarter by applying a statutorily defined formula to drug pricing data. Due to the proprietary nature of the pricing data used in these calculations, 340B ceiling prices are not made public.

The 340B providers benefiting from these discounted prices include such safety-net providers as community health centers and hospitals that serve a disproportionate number of low-income patients. In 2010, the Affordable Care Act expanded the types of providers eligible to participate in the 340B program to include children's hospitals, critical access hospitals, free-standing cancer hospitals, rural referral centers, and sole community hospitals. As of January 1, 2018, the 340B program included 12,823 providers and 29,663 associated sites, for a total 42,486 registered sites.[4]

The 340B program intersects with State Medicaid programs in important ways. One way relates to how State Medicaid programs reimburse 340B providers for drugs provided to Medicaid beneficiaries. In February 2016, the Centers for Medicare & Medicaid Services (CMS) clarified that State Medicaid agencies should reimburse providers for drugs purchased under the 340B program at actual acquisition costs and recognized the 340B ceiling price plus a dispensing fee to be an acceptable measure of actual acquisition costs.[5] However, States currently do not have access to the 340B ceiling price as it is protected by confidentiality rules. Another way relates to how States claim Medicaid rebates from drug manufacturers. In general, States are entitled to statutorily defined rebates from manufacturers for covered outpatient drugs. However, "duplicate discounts"—which occur when drug manufacturers pay rebates to State Medicaid agencies on drugs that they sold at the already discounted 340B price—are prohibited by law.[6]

Oversight of the 340B Program Has Improved Over the Years, But Some Key Challenges Persist

Across numerous OIG reviews of the 340B program, our work has identified program integrity vulnerabilities, many of which have been addressed, but others continue to be concerns.[7] Our initial work, released in the early 2000s, found deficiencies in HRSA's oversight of the program. These deficiencies included inaccurate information regarding which providers were eligible for discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. Systematic monitoring by HRSA was critical, at the

[4] HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, p. 259.
[5] 81 Fed. Reg. 5170, 5317 (February 1, 2016); 42 C.F.R. § 447.518(a)(2).
[6] 42 U.S.C. § 256b(a)(5)(A)(i); 42 U.S.C. § 1396r-8(j)(1).
[7] OIG has issued seven evaluations of the 340B program: (1) *Deficiencies in the 340B Drug Pricing Program's Database*, OEI-05-02-00071, June 2004; (2) *Deficiencies in Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, October 2005; (3) *Review of 340B Prices*, OEI-05-02-00073, July 2006; (4) *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs*, OEI-05-09-00321, June 2011; (5) *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014; (6) *Medicaid Drug Rebate Dispute Resolution Could Be Improved*, OEI-05-11-00580, August 2014; and (7) *State Efforts to Exclude 340B Drugs From Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.

time, because confidentiality protections prevented HRSA from sharing the ceiling prices with 340B providers. This lack of transparency left 340B providers unable to determine whether they were paying accurate amounts to drug manufacturers. Further, HRSA lacked the necessary enforcement tools for holding manufacturers accountable.

In the years following OIG's initial work, HRSA took steps to improve oversight of the 340B program and was granted additional oversight authorities. HRSA issued several technical assistance resources to facilitate compliance among manufacturers and 340B providers. For example, HRSA created a training webinar for 340B providers to help them ensure compliance with program requirements to prevent duplicate discounts when working with Medicaid patients. In 2010, legislation directed HRSA to further define standards for calculating 340B ceiling prices and to share those ceiling prices with 340B providers. HRSA was also granted new enforcement tools, including authority to conduct audits of both manufacturers and 340B providers and to impose civil monetary penalties for manufacturers that knowingly and intentionally overcharge 340B providers.[8]

Some of HRSA's efforts to implement its new oversight authorities and clarify program rules through regulations were either unsuccessful or remain unfinished. For example, HRSA developed a proposed omnibus 340B regulation in 2014, but withdrew it prior to publication after a Federal court ruling established limits on HRSA's rulemaking authority for the 340B program. In 2015, HRSA instead issued proposed omnibus 340B guidance that would have addressed a number of OIG and Government Accountability Office recommendations, such as clarifying the definition of a patient.[9] However, HRSA never finalized this guidance, and formally withdrew it in January 2017. HRSA also issued a final regulation on standards for calculating 340B ceiling prices and civil monetary penalties for manufacturers in January 2017.[10] However, HRSA has delayed the effective date of that regulation multiple times, including its most recent proposal to delay the effective date until July 2019, and has indicated that it intends to revisit the substance of the issues involved.[11]

Despite progress in addressing some program vulnerabilities, the steps HRSA has taken do not fully address the long-standing challenges identified by OIG. As such, OIG continues to recommend improving the 340B program by increasing transparency and clarifying program rules. HRSA, CMS, and Congress each have roles in advancing these improvements. These broad areas, and the specific recommendations OIG has made to address each, are explored in detail below.

OIG RECOMMENDS: Increasing Transparency to Allow Payment Accuracy

Transparency is needed to support payment accuracy in two ways. First, 340B providers and State Medicaid programs need to know the 340B ceiling prices to determine whether they are paying the correct amount. Second, State Medicaid programs need to know which Medicaid

[8] Affordable Care Act, P.L. 111-148 § 7102(a).
[9] 80 Fed. Reg. 52300 (August 28, 2015).
[10] 20 Fed. Reg. 1210 (January 5, 2017).
[11] 83 Fed. Reg. 20008 (May 7, 2018).

claims are associated with 340B drugs to pay 340B providers accurately and ensure that they collect all appropriate drug rebates without subjecting manufacturers to duplicate discounts. The current lack of transparency regarding both 340B prices and Medicaid claims hampers payment accuracy in both of these areas.

The lack of transparency in ceiling prices impedes 340B providers and Medicaid programs from ensuring that they have paid the correct amount for 340B drugs.

Although Congress authorized HRSA to share confidential ceiling prices with 340B providers in 2010, HRSA has not yet done so.[12] HRSA received funding to support this effort in fiscal year 2014. Since then, HRSA has been developing a secure pricing system, which it plans to use as a single point of reference for calculating, verifying, and displaying 340B ceiling prices. According to HRSA's plans, 340B providers will be able to access the system to view 340B ceiling prices and verify that they are paying at or below the posted 340B ceiling price. Manufacturers will also be able to upload their quarterly pricing data and validate their prices with the HRSA-verified 340B ceiling price. HRSA identified this initiative as a priority for fiscal year 2018, and has done so again for fiscal year 2019.[13, 14] Until the system is operational, 340B providers cannot ensure that they are paying the right amount.

The 2010 legislation addressed access to ceiling prices for 340B providers, but it did not address access for State Medicaid agencies. Lack of access to 340B ceiling prices can prevent State Medicaid agencies from effectively enforcing Medicaid payment policies for 340B drugs. OIG found that without access to 340B ceiling prices, States are unable to implement automated, prepayment edits to enforce these policies. Instead, some States conduct labor-intensive and costly audits and post-payment reviews in an attempt to ensure that they have paid 340B providers correctly for 340B drugs. HRSA agreed that ceiling prices should be shared with States, but needs additional statutory authority to do so.[15]

The lack of transparency around which Medicaid claims are associated with 340B drugs hinders States' efforts to correctly apply their 340B payment policies and to claim correct Medicaid rebates from manufacturers.

States also need transparency into which Medicaid claims are associated with 340B drugs to ensure that they make payments in accordance with their payment policies. Even if States can determine *how much* they should be paying 340B providers for 340B drugs, they still may not know *which claims* to reimburse at that rate.

Likewise, knowing which Medicaid claims are associated with 340B drugs is essential for States to correctly and separately claim rebates from manufacturers. If States cannot correctly identify 340B claims, two types of problems may result. One, States may inappropriately *include* 340B

[12] Affordable Care Act, P.L. 111-148 § 7102(a).
[13] HRSA, *Fiscal Year 2018 Justification of Estimates for Appropriations Committees*, p. 245.
[14] HRSA, *Fiscal Year 2019 Justification of Estimates for Appropriations Committees*, p. 258.
[15] OIG, State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs, OEI-05-09-00321, June 2011.

claims in rebate invoices sent to manufacturers, potentially causing duplicate discount situations. Two, States may inappropriately *exclude* 340B claims and forgo rebates to which they are entitled. In addition, without reliable methods for identifying 340B claims, States may be more likely to have rebate disputes with drug manufacturers, which require additional resources to resolve and may impede or delay rebate payments.

HRSA maintains a tool, the Medicaid Exclusion File, to assist States in identifying providers who have chosen to dispense 340B drugs to Medicaid patients in the fee-for-service program. OIG found that in 2015, States typically used HRSA's Medicaid Exclusion File to identify and exclude 340B claims for the purpose of collecting rebates.[16] However, we found that this provider-level approach may not accurately identify all individual 340B claims, creating a risk of duplicate discounts and forgone rebates. We found that methods that operate at the claim level can improve accuracy in identifying 340B claims and thereby help prevent duplicate discounts and improve collection of rebates. Identifying and excluding 340B claims paid by Medicaid managed care organizations involves additional complications, and claim-level transparency would help address these challenges, too.

To increase transparency, OIG recommends that CMS require States to use claim-level methods to identify 340B claims. CMS did not concur with OIG's recommendation to require the use of claim-level methods to identify 340B claims, stating that it agreed with the importance of claim-level methods but that the statute "does not contemplate" placing such a requirement on State Medicaid agencies. CMS noted that States may develop their own billing instructions in accordance with requirements in the Public Health Services Act. In State Program Release No. 161, CMS informed States about tools they can use to identify 340B claims, including National Council for Prescription Drug Plans Telecommunication Standards that some States have instructed 340B providers to use.

Notably, CMS took steps in late 2017 to increase transparency for 340B claims submitted to Medicare. In its Outpatient Prospective Payment System payment rule for calendar year 2018, CMS began requiring hospitals to use claim-level modifiers when billing for 340B drugs, which was needed to implement its new 340B-specific reimbursement policy.[17]

OIG RECOMMENDS: Clarifying Rules to Ensure That the 340B Program Operates as Intended

OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements. Contract pharmacies are external pharmacies (often retail pharmacies) that partner with 340B providers to dispense 340B drugs to the providers' patients, and their prevalence is on the rise. These pharmacies typically dispense both 340B drugs on behalf of 340B providers, as well as non-340B drugs. The operations of contract pharmacies are often quite complex, and this complexity has important consequences. In particular, it leads to variation in eligibility determinations across different 340B providers. It also leads to inconsistencies in whether uninsured patients benefit directly from the 340B program. As such,

[16] OIG, *State Efforts to Exclude 340B Drugs from Medicaid Managed Care Rebates*, OEI-05-14-00430, June 2016.
[17] 82 Fed. Reg. 59216 (December 14, 2017).

OIG recommends that HRSA clarify rules to address these ambiguities and inconsistencies.

HRSA initiated steps to address OIG's concerns by proposing updates and clarifications that address the patient definition, contract pharmacy arrangements, and other program integrity provisions in its 2015 proposed omnibus 340B guidance. However, HRSA never finalized that proposed guidance. As such, these issues remain unaddressed. To address these issues through rulemaking, HRSA needs additional statutory authority.

HRSA's current patient definition guidance does not account for the complexity of contract pharmacy arrangements.

340B providers are prohibited by law from dispensing 340B drugs to anyone who is not their patient.[18] However, the law does not define what constitutes a "patient." HRSA's official definition of patient eligibility comes from guidance issued before 340B providers were permitted to contract with networks of retail pharmacies. That guidance specifies that an individual is an eligible patient only if he or she has an established relationship with the 340B provider, he or she receives health care services from the 340B provider, and those services are consistent with the service or range of services for which Federal funding is being granted.[19, 20]

Dispensing a 340B drug to an ineligible patient, which is prohibited by law, is referred to as "diversion." Thus, appropriately determining patient eligibility for 340B drugs is critical to preventing diversion.

Although the law and HRSA guidance focus on 340B eligibility at the patient level, operationally, contract pharmacies determine eligibility at the prescription level. Retail contract pharmacies often have no way to distinguish a 340B patient from any other customer filling a prescription at their stores. To address this reality, many contract pharmacies dispense drugs to all of their customers—340B-eligible or otherwise—from their regular inventory. Only later, after dispensing a drug, do these contract pharmacies determine which prescriptions were given to 340B-eligible patients. They then order the appropriate quantity of drugs at 340B prices to replenish their inventory.

To identify which prescriptions were given to 340B-eligible patients, contract pharmacies often match information from the 340B providers, such as patient and prescriber lists, to their dispensing data. In its 2014 report, OIG found wide variation in these eligibility determinations. Different determinations of 340B eligibility appear to stem from the application of the patient definition by 340B providers and their contract pharmacies to a wide variety of prescription-level scenarios.[21] Depending on the interpretation of HRSA's patient definition, some 340B provider

[18] 42 U.S.C. § 256b(a)(5)(B).
[19] Disproportionate share hospitals (DSHs) are exempt from the requirement that services be consistent with the service or range of services for which Federal funding is being granted. DSHs serve a significantly disproportionate number of low-income patients and receive payments from CMS to cover the costs of providing care to uninsured patients. DSHs are defined in Section 1886(d)(1)(B) of the Social Security Act.
[20] 61 Fed. Reg. 55156, 55157-8 (October 24, 1996).
[21] OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

eligibility determinations would be considered diversion and others would not.

HRSA's current guidance on patient definition does not account for many of the 340B eligibility decisions that arise in contract pharmacy arrangements. The following example illustrates how contract pharmacy operations have led to different determinations of 340B eligibility in the absence of a clearer patient definition.

> ***Scenario: Nonexclusive physician***
>
> *A physician practices part time at a 340B provider, but also has a private practice. The physician first sees an individual at the 340B provider. Separately, the physician sees the same individual at his private practice and writes a prescription for that person. The individual fills the prescription at the 340B provider contract pharmacy—even though the prescription was provided at a private practice. Should the patient be considered 340B-eligible*?

Whether contract pharmacies determine the prescription in this scenario to be 340B-eligible depends on how they match their dispensing data to information from the 340B provider. One 340B provider in OIG's report noted that it would automatically categorize the prescription in this scenario as 340B-eligible because it uses a list of all prescribers working at the 340B provider to identify 340B-eligible prescriptions. Because the physician in this scenario would be on the prescriber list, the prescription would be categorized as 340B-eligible, even though it was written at the physician's private practice (i.e., it originated outside the 340B provider).

Another 340B provider in OIG's report noted that it would *not* categorize the prescription in that scenario as 340B-eligible because, although the 340B provider's contract pharmacy also uses a prescriber list to identify 340B-eligible prescriptions, it limits the prescriber list only to those prescribers who work exclusively for the 340B provider. Because the physician in this scenario would not be on the prescriber list (as he does not work exclusively for the 340B provider), the prescription would not be categorized as 340B-eligible.

In its 2015 proposed omnibus guidance, HRSA proposed an update to the patient definition that could have addressed this scenario and many others. The guidance proposed a six-part patient definition, to be applied on a prescription-by-prescription basis, that would have deemed prescriptions to be 340B-eligible only if they resulted from a service (e.g., a physician consultation) provided by a 340B provider. However, HRSA never finalized this guidance, and formally withdrew it in January 2017. HRSA made no public comment as to why the guidance was withdrawn.

Neither the 340B statute nor HRSA guidance addresses whether 340B providers must offer the discounted price to uninsured patients.

Despite the 340B program's goal of increasing access and providing more comprehensive care, neither the 340B statute nor HRSA guidance speaks to how 340B providers must use savings

from the program—nor do they stipulate that the discounted 340B price must be passed on to uninsured patients.

Given this discretion, some 340B providers have chosen to institute extra measures to ensure that uninsured patients benefit through lower drug costs when filling prescriptions at contract pharmacies. If they do not, uninsured patients can pay full price for drugs filled at contract pharmacies and thus not directly benefit from the 340B discount on their prescriptions. Guidance on how the program should apply to uninsured patients in these scenarios should be clarified to ensure that patients are treated consistently across 340B providers and that operations align with the program's intent.

In OIG's 2014 report on 340B contract pharmacy arrangements, we found that a few 340B providers did not offer the discounted price to their uninsured patients at contract pharmacies.[22] These 340B providers' contract pharmacy arrangements would have required additional processes to identify uninsured patients as 340B-eligible because, as previously noted, many contract pharmacies do not know which patients are from the 340B providers when they come to the pharmacy. Not knowing whether the patient is 340B-eligible may not have a financial impact on insured patients, because their costs are often determined by standard copayments stipulated in their insurance plans. For uninsured patients, not knowing whether they are 340B-eligible means that they may be charged the full price for their drugs. Contract pharmacies may later identify uninsured patients' prescriptions as 340B-eligible, but those patients will have paid full price.

Conclusion and Specific OIG Recommendations

We appreciate the Committee's interest in these important issues. We also appreciate the progress that HRSA has made to improve its oversight of the 340B program. We continue to urge HRSA, in coordination with CMS, to increase transparency and clarify program rules. Within these themes, we have made the following recommendations.

Increase transparency to allow payment accuracy

- HRSA should fully implement its authority to share ceiling prices with 340B providers.
- HRSA should work with CMS to share ceiling prices with State Medicaid agencies.
- CMS should require State Medicaid agencies to use claim-level methods to identify 340B claims and HRSA should update its related guidance.

Clarify rules to ensure that the program operates as intended

- HRSA should clarify the definition of eligible patient.
- HRSA should address whether 340B providers must offer discounted 340B prices to uninsured patients.

HRSA and CMS have both stated that they do not have sufficient statutory authority to carry out most of these recommendations. Therefore, we encourage Congress to consider making

[22] OIG, *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

statutory changes that would provide HRSA broader regulatory power, as outlined in the fiscal year 2019 President's budget.[23] This would improve program operations and increase clarity in program goals, enabling more effective oversight of this valuable program.

Thank you for the opportunity to testify and participate in the discussion on ways to improve oversight of the 340B program. OIG will continue to work with HRSA, CMS, and Congress to protect the integrity of this program and help ensure that it is efficiently and effectively meeting its intended goals.

[23] Office of Management and Budget, *Budget of the United States Government for Fiscal Year 2019: An American Budget.* Accessed at https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf on May 9, 2018.