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Committee on Energy and Commerce:
Subcommittee on Health**

“Examining the 340B Drug Pricing Program”

Testimony of:

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Good morning Chairman Pitts, Ranking Member Green, and members of the Subcommittee. 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 (HHS). I appreciate the opportunity to appear before you to discuss the integrity of the 340B Drug Pricing Program (340B program).

In 1992, Congress enacted section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. 256b, to establish the 340B program, which is managed by the Health Resources and Services Administration (HRSA). The program was created to generate savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at discounted prices. These savings could then be used to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”¹ HRSA estimated that the annual savings attributable to the 340B program in 2013 was \$3.8 billion.²

Pursuant to the PHS Act, drug manufacturers sign a Pharmaceutical Pricing Agreement stipulating that they will charge certain eligible health care providers (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 confidential drug pricing data. 340B providers benefiting from these discounted prices include such safety-net providers as community health centers, critical access hospitals, and hospitals that serve a disproportionate number of low-income patients. As of February 28, 2015, 11,180 providers were participating in the 340B program.

For over a decade, OIG has performed evaluations and audits reviewing HRSA’s oversight of the 340B program and various other aspects of the 340B program to ensure that it was meeting its intended goals.³ Our initial work, released in the early 2000s, found numerous deficiencies in HRSA’s oversight of the program. These deficiencies included inaccurate information about which providers were eligible for the discounted prices and a lack of systematic monitoring to ensure that drug manufacturers were charging 340B providers the correct prices. In the latter case, confidentiality protections prevented HRSA from sharing the ceiling prices with the 340B providers, leaving them in the dark as to whether they were being charged correctly by drug manufacturers. Furthermore, we also pointed out that

¹ H.R. Rept. No. 102-384 (Part 2), at 12 (1992) (Conf. Rept.).

² The U.S. Department of Health and Human Services. *HRSA FY2015 Budget Justification*.

³ OIG has issued five evaluations on 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; and (5) *Contract Pharmacy Arrangements in the 340B Program*, OEI-05-13-00431, February 2014.

HRSA lacked the necessary enforcement tools for dealing with compliance violations.

In response, HRSA has significantly strengthened its oversight of the 340B program. In addition, Congress took action to improve program integrity, including authorizing HRSA to share the discounted ceiling prices with 340B providers as well as empowering HRSA with new enforcement tools. HRSA's actions and the statutory changes to the 340B program addressed many of OIG's recommendations.

However, despite these improvements, the 340B program faces continuing challenges. In this testimony, OIG recommends further improving the 340B program by: (1) increasing transparency, and (2) clarifying program rules. These recommendations are explored in detail below.

OIG RECOMMENDS INCREASED TRANSPARENCY TO SUPPORT OVERSIGHT AND STRENGTHEN PROGRAM INTEGRITY

More transparency is needed in both 340B ceiling prices and Medicaid claims for 340B-purchased drugs. OIG's work on the 340B program has consistently found that a lack of transparency in both 340B ceiling prices and Medicaid claims for 340B-purchased drugs has negatively affected 340B providers, State Medicaid programs, and drug manufacturers.

The lack of transparency in prices prevents 340B providers and Medicaid from ensuring that they have paid the correct amount for 340B-purchased drugs.

Currently, neither 340B providers nor States Medicaid agencies have access to 340B ceiling prices. Because of confidentiality provisions in the Medicaid statute that protect manufacturer pricing data, HRSA previously could not share ceiling prices with 340B providers. Consistent with an OIG recommendation, Congress, as part of the Affordable Care Act (ACA), authorized HRSA to share ceiling prices with 340B providers; however, HRSA has not yet established a mechanism to do so. These same confidentiality provisions continue to prevent HRSA from sharing 340B ceiling prices with States.

Without access to ceiling prices, 340B providers cannot ensure that they are being charged the appropriate amount by drug manufacturers. OIG's work has shown that 340B providers have, in fact, been overcharged for 340B-purchased drugs in the past: we found that 14 percent of drug purchases under the 340B program in June 2005 exceeded applicable ceiling prices; as a result, 340B providers overpaid by a total of \$3.9 million during that month.⁴

Lack of access to 340B ceiling prices also prevents States Medicaid agencies from effectively enforcing their Medicaid payment policies for 340B-purchased drugs. States pay for 340B-purchased drugs when 340B providers dispense them to Medicaid patients. Many States have established Medicaid policies to pay for 340B-purchased drugs at 340B providers' actual acquisition cost; these policies ensure that Medicaid realizes savings from the discounted 340B prices. However, 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 potentially costly audits and post-payment reviews in an attempt to ensure that they have paid 340B providers correctly for 340B-purchased drugs.

⁴ OIG, *Review of 340B Prices* (OEI-05-02-00073), July 2006.

OIG recommends HRSA share 340B ceiling prices with 340B providers and State Medicaid agencies

Making 340B ceiling prices transparent to 340B providers and to State Medicaid agencies would enable them to ensure that they have paid the correct amounts for 340B-purchased drugs.

HRSA has made improvements in 340B ceiling price transparency, but more action is needed to implement outstanding OIG recommendations. The ACA directed HRSA to share ceiling prices with 340B providers via a secure Web site. HRSA initially indicated that it could not do so given limited funding, but announced that it would move forward with the project after receiving increased appropriations in 2014. The ACA also required HRSA to take additional steps, such as spot checks of sales records, to ensure that 340B providers are not overcharged for 340B-purchased drugs. The ACA did not, however, authorize HRSA to share 340B ceiling prices with *States*; additional legislative authority would be required to do so.

The lack of transparency regarding which Medicaid claims represent 340B-purchased drugs limits States' efforts to pay correctly and prevent duplicate discounts.

In addition to needing greater transparency concerning 340B ceiling prices, States need greater transparency as to which Medicaid claims represent 340B-purchased drugs to enforce their Medicaid payment policies. The increasing complexity of 340B program operations, including contract pharmacy arrangements, has made it more difficult for States to accurately identify these claims. This means that even if States can determine *how much* they should be paying 340B providers for 340B-purchased drugs, they still may not know *which claims* to reimburse at that rate.

Transparency as to which Medicaid claims represent 340B-purchased drugs is also a critical component of preventing duplicate discounts. Subjecting drug manufacturers to duplicate discounts on 340B-purchased drugs is prohibited by law. Duplicate discounts occur when drug manufacturers pay State Medicaid agencies rebates under the Medicaid drug rebate program on drugs they sold at the already-discounted 340B price.

When States invoice manufacturers for Medicaid drug rebates, they exclude claims representing 340B-purchased drugs from invoices to prevent duplicate discounts. States must therefore be able to accurately identify these claims to prevent duplicate discounts from occurring. HRSA maintains a tool, the Medicaid Exclusion File, to assist States in this process. However, OIG has found the use and value of this tool to be limited. Specifically, we found that in 2010 over half of States had developed alternatives to the Medicaid Exclusion File, and many cited inaccuracies in the Medicaid Exclusion File as a reason for doing so.⁵

⁵ OIG, *State Medicaid Policies and Oversight Activities Related to 340B-Purchased Drugs* (OEI-05-09-00321), June 2011.

The ACA's extension of Medicaid rebates to drugs paid through Medicaid managed care organizations (MCOs) has further complicated the process of identifying Medicaid claims for 340B-purchased drugs to prevent duplicate discounts. The share of all Medicaid beneficiaries covered by Medicaid MCOs has increased significantly in recent years, from approximately 58 percent in 2002 to approximately 74 percent of beneficiaries in 2011.⁶ HRSA issued a policy release in December 2014 to clarify that the Medicaid Exclusion File is intended for use only with fee-for-service Medicaid, not Medicaid MCOs; however, HRSA has not developed or officially endorsed any alternative tools for use with Medicaid MCOs.⁷ Additionally, OIG's 2014 report on 340B contract pharmacy arrangements found that difficulties in identifying beneficiaries covered by Medicaid MCOs contribute to duplicate discount vulnerabilities.⁸ OIG has work underway that will assess States' current methods of preventing duplicate discounts for drugs paid through Medicaid MCOs.

OIG recommends HRSA improve tools and guidance to help States and drug manufacturers identify which Medicaid claims have received the 340B discount

Transparency as to which Medicaid claims represent 340B-purchased drugs would further enhance States' efforts to pay correctly and would help them protect manufacturers from duplicate discounts.

Although HRSA and CMS have made progress in this area, OIG encourages HRSA and CMS to continue working with 340B providers and State Medicaid agencies to improve claims transparency. In response to OIG's recommendation, HRSA started collecting new information as part of 340B providers' annual recertification to improve the accuracy of the Medicaid Exclusion File. Also in response to an OIG recommendation, CMS issued guidance to States on alternate ways to identify claims for 340B-purchased drugs. OIG's ongoing work on preventing duplicate discounts for drugs paid through Medicaid MCOs may result in additional recommendations to improve claims transparency.

OIG RECOMMENDS CLARIFYING 340B PROGRAM RULES TO SUPPORT OVERSIGHT AND STRENGTHEN PROGRAM INTEGRITY

Since 2010, 340B providers have increasingly used contract pharmacies to dispense 340B-purchased drugs on their behalf. Contract pharmacies are external pharmacies (often retail pharmacies) that partner with 340B providers to dispense 340B-purchased drugs to the providers' patients. In its 2014 report, OIG found that the percentage of all 340B providers that use contract pharmacies had risen from 10 percent to 22 percent since 2010. Moreover, the number of unique pharmacies serving as 340B contract pharmacies had grown by 770 percent.⁹

⁶ Centers for Medicare & Medicaid Services (CMS), *Medicaid Managed Care Enrollment Report*, July 2011.

⁷ HRSA, *Clarification on Use of the Medicaid Exclusion File*, December 12, 2014.

⁸ OIG, *Contract Pharmacy Arrangements in the 340B Program* (OEI-05-13-00431), February 2014.

⁹ *Ibid.*

OIG has identified a number of challenges and inconsistencies arising from the widespread use of contract pharmacy arrangements. Their operations are often quite complex, and this complexity has important consequences—variation in eligibility determinations across different 340B providers and inconsistencies in whether uninsured patients benefit directly from the 340B program.

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-purchased drugs to anyone who is not their patient. However, the law does not further 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.¹⁰

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

Although the law and HRSA guidance currently define 340B eligibility at the patient level, operationally, contract pharmacies determine eligibility at the prescription level. Retail contract pharmacies generally 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 by 340B providers and their contract pharmacies of the patient definition to a wide variety of prescription-level scenarios. Depending on the interpretation of HRSA’s patient definition, some 340B provider 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:

¹⁰ Disproportionate share hospitals are exempt from the requirement that services be consistent with the service or range of services for which Federal funding is being granted.

Scenario: Nonexclusive physician

A physician practices part time at a 340B entity, but also has a private practice. The physician first sees an individual at the 340B entity. On a separate occasion, the physician sees the same individual at his private practice and writes a prescription for the individual. The individual fills the prescription at the 340B entity's contract pharmacy.

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., originated outside the 340B provider).

Another 340B provider in OIG's report noted that it would *not* categorize the prescription in this 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 to only 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.

Yet another 340B provider in OIG's report noted that it may or may not categorize the prescription in this scenario as 340B-eligible, on the basis of a manual review. Prescriptions from nonexclusive physicians go into a queue for 340B provider staff to review and categorize as 340B-eligible or not 340B-eligible.

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

Despite the 340B program's ultimate goal of increasing access and providing more comprehensive care, neither the 340B statute nor HRSA guidance speak 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.

Several 340B providers in OIG's 2014 report did not offer the 340B price to their uninsured patients at contract pharmacies. 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. OIG did not assess the specific consequences for insured patients in its report. For uninsured patients, not knowing whether the patient is 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 already paid full price.

OIG work suggests clarifications to the 340B program rules are needed in these areas:

- Clarifying HRSA guidance on patient definition as it applies to different prescription-level transactions. This could address challenges that arise from different interpretations of the current guidance, help to improve program integrity, and ensure that the program is achieving its intended outcomes.
- Further guidance on how 340B discounts should apply to uninsured patients at contract pharmacies.

HRSA has announced plans to issue wide-ranging 340B program guidance, in June 2015, that will address patient definition and other contract pharmacy issues.

Although OIG work has focused on the potential benefits of additional guidance in relation to contract pharmacy arrangements, such guidance would also benefit the 340B program more generally.

CONCLUSION

We appreciate the Subcommittee's interest in these important issues. Further, we are encouraged by HRSA's response to our recommendations and the progress it has made thus far in improving its oversight of the 340B program. We continue to urge HRSA to fully address OIG's recommendations related to improving transparency of 340B pricing information for 340B entities and State Medicaid agencies and improving transparency of 340B claims. It is also important that HRSA strengthen and clarify program rules regarding how the 340B discount should be applied. Without clear rules, HRSA oversight is compromised, interpretations of program rules vary, and vulnerabilities in 340B program integrity will persist.

OIG is committed to continued oversight of this program. Ongoing OIG work is assessing the prevention of duplicate discounts for drugs paid through Medicaid MCOs. Additional OIG work underway is examining the intersection of the 340B program and Medicare

Part B. We anticipate final reports on these issues in 2015, and we look forward to sharing those results with the Committee at that time. This concludes my testimony. I would be happy to answer your questions. Thank you.