Testimony of:
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Good afternoon, Mr. Chairman and members of the subcommittee. I am Stuart Wright, Deputy Inspector General for Evaluation and Inspections for the Office of Inspector General (OIG), U.S. Department of Health and Human Services (HHS). I am pleased to have Ann Maxwell, Acting Regional Inspector General from our Chicago office, with me today. I appreciate the opportunity to appear before you to present information regarding the 340B Drug Pricing Program (340B program), which establishes ceiling prices on prescription drugs that are purchased by certain health care entities.

Over the past few years, OIG has issued a number of audit and evaluation reports looking at various aspects of the 340B program. Our most recently published work, "Deficiencies in the Oversight of the 340B Drug Pricing Program," assessed the effectiveness of existing systems and processes that are intended to ensure that entities participating in the program are able to purchase products at or below a statutorily established ceiling price. Currently, we are engaged in another evaluation of the program to determine whether entities participating in the 340B program have actually received the ceiling prices to which they are entitled, and if not, the potential reasons for price discrepancies. Our work has led us to conclude that the 340B program may not be functioning as intended to ensure that appropriate discounts on drugs are available to eligible entities. We have found a number of deficiencies in oversight of the program and have concerns related to broader programmatic issues that negatively impact the program.

My testimony begins with a brief overview of the program, followed by a summary of OIG findings and recommendations that are aimed at improving the 340B program.

BACKGROUND ON THE 340B DRUG PRICING PROGRAM

In 1992, Congress enacted section 340B of the Public Health Service Act (PHS Act), 42 U.S.C. 256b, to establish the 340B Drug Pricing Program. This program, which is managed by the Health Resources and Services Administration (HRSA), provides for sales of drugs at or below established ceiling prices to certain "covered entities" (340B entities) that provide health care to some of the country's most disadvantaged citizens who are typically uninsured or underinsured. 340B entities include such health care entities as public hospitals, AIDS Drug Assistance programs, and community health centers. Based on the most recent HRSA estimates, 340B entities spent $4 billion on covered outpatient drugs in calendar year 2005.

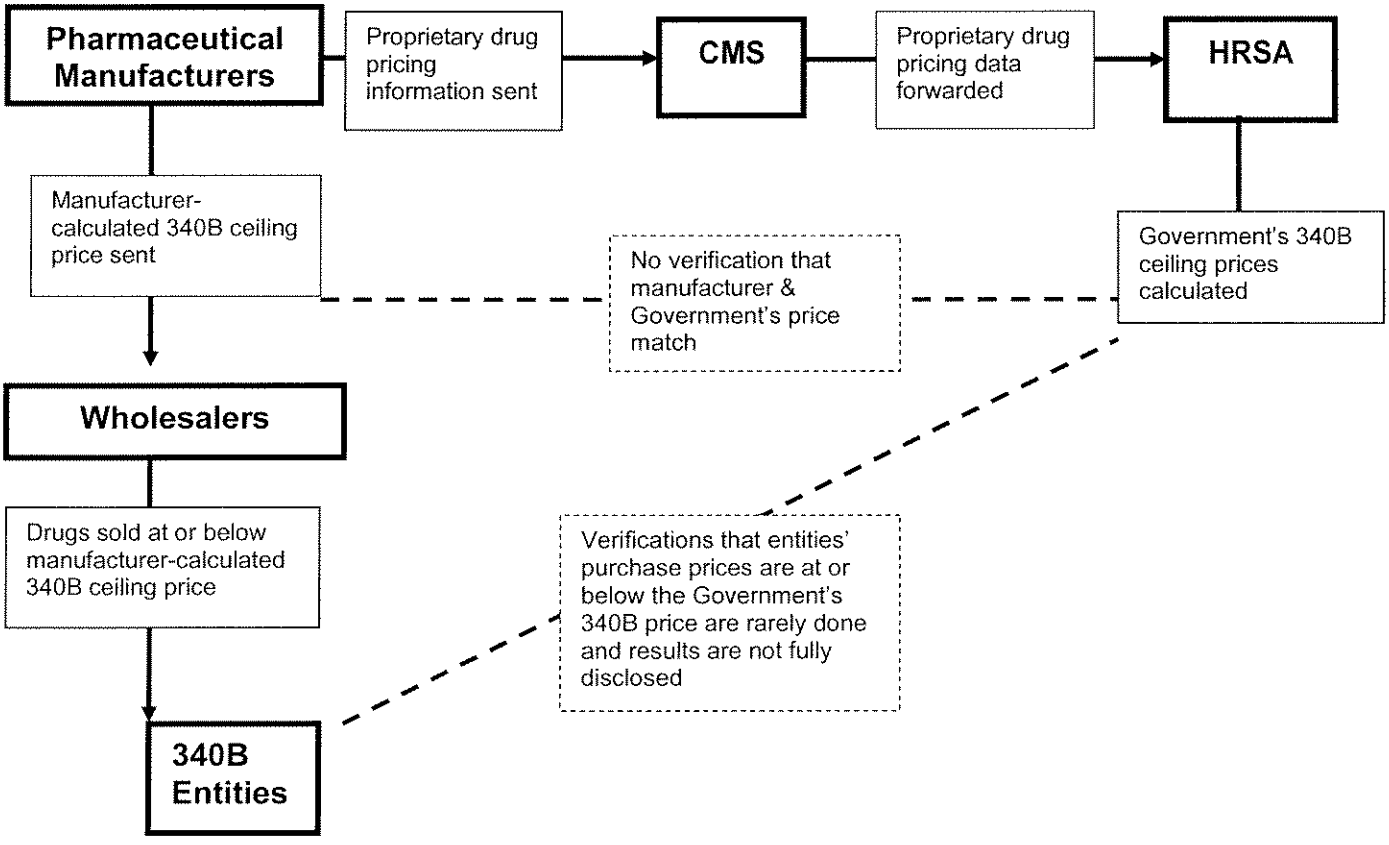
Pursuant to the PHS Act, manufacturers sign a Pharmaceutical Pricing Agreement (Agreement) stipulating that they will charge 340B entities at or below a specified maximum price, known as the 340B ceiling price, for covered outpatient drug purchases.

Ceiling prices are guaranteed whether the 340B entity purchases drugs directly from manufacturers or through a wholesaler.

The Government and pharmaceutical manufacturers separately calculate 340B ceiling prices each quarter. The Government's calculations are intended for use in program oversight, while the manufacturers' calculations are the prices used in sales to 340B entities. Both the Government and the manufacturers calculate 340B ceiling prices using the same statutorily-defined formula and the drug pricing data that manufacturers report to the Centers for Medicare & Medicaid Services (CMS) for the purposes of the Medicaid drug rebate program.

Due to statutory provisions and policies protecting the manufacturers' pricing data, neither the Government's nor the manufacturers' ceiling prices are disclosed to the covered entities. Instead, 340B entities pay the prices they are billed by the manufacturer or wholesaler with no way to verify that they are being charged at or below the 340B ceiling prices to which they are entitled. The chart below illustrates the current flow of 340B ceiling price calculations in the purchase of drugs and oversight of the program. The dotted lines represent where program oversight should be strengthened, as I will discuss further.

Calculation of the 340B Ceiling Price and Purchase Flow



340B PROGRAM OVERSIGHT ISSUES

Calculating the 340B Ceiling Price

For many years CMS calculated the 340B ceiling prices used by the program. More recently, HRSA assumed that responsibility. HRSA needs the 340B ceiling prices for research, analysis, audit, and dispute resolution purposes. However, OIG has found systemic problems with the accuracy and reliability of the Government's historical record of 340B ceiling prices. For example, for over a decade, the Government's 340B ceiling prices were calculated using incomplete data to represent package size. HRSA has not established any standards or technical guidance on using the statutorily-defined formula to calculate 340B ceiling prices.

Problems with reliability and accuracy also stem from missing data. When any of the drug pricing elements needed to calculate a ceiling price are missing, an accurate 340B ceiling price cannot be calculated, and HRSA cannot create an accurate record of ceiling prices for program oversight purposes. Missing ceiling prices are most often the result of manufacturers not reporting to CMS, or not reporting in a timely manner, the drug pricing data necessary for the calculation. While HRSA is eventually provided the missing data when they are submitted by the manufacturer to CMS at a later date, HRSA does not have a policy in place to update the ceiling prices when supplemental data are received. Thus, any missing data elements or 340B ceiling prices simply remain missing. OIG found that HRSA did not have 340B ceiling prices for nearly 30 percent of eligible drugs due to missing data. Another 8 percent of 340B ceiling prices were calculated incorrectly due to missing data.

Monitoring of 340B Program Participation

Based on our review, we concluded that 340B entities' participation in the program is not adequately monitored. HRSA is required to maintain a complete listing of all its participating 340B entities. This permits pharmaceutical manufacturers to verify entities' eligibility for the discount and ensure that their drugs are only shipped to legitimate sites. However, in a June 2004 report, "Deficiencies in the 340B Drug Discount Program's Database," we found that HRSA's participant database inappropriately listed 38 percent of sampled entities as participating in the program when, in fact, they did not. Additionally, we found that the database had incorrect address information for 43 percent of sampled entities. The inaccuracies in the participant database limits HRSA's ability to ensure that only legitimate entities are receiving the 340 ceiling prices.

Ensuring That 340B Entities Pay 340B Ceiling Prices or Below

OIG also found that there is no systematic oversight process in place to ensure that 340B entities receive the ceiling prices to which they are legally entitled. HRSA does not monitor the purchase prices paid by 340B entities to ensure that they are at or below the

Government's 340B ceiling prices. Conducting this type of oversight is essential to ensure that Federal grant dollars are spent appropriately.

Rather than establishing a systematic means of monitoring prices, HRSA generally checks the appropriateness of 340B entities' prices only when requested by the entity to do so. An entity may submit a written request to HRSA to conduct a review for a maximum of 10 products. If HRSA agrees to undertake the review, the results will only confirm or refute that the entity has been overcharged. HRSA does not convey the extent of any overcharges due to confidentiality concerns.

Overseeing the Drug Industry's 340B Ceiling Price Calculations

OIG found that HRSA does not verify that manufacturers are correctly calculating 340B ceiling prices. It is especially important for HRSA to monitor manufacturers' ceiling price calculations because the 340B entities are not permitted access to ceiling prices themselves, and therefore cannot perform their own checks. Specifically, HRSA does not compare the Government's 340B ceiling prices to the manufacturers' ceiling prices to ensure that the results are the same. Theoretically, HRSA and manufacturers should calculate the same 340B ceiling prices because they use the same drug pricing elements for the calculation. However, this may not be the case due to differing interpretations of the drug pricing data used in the formula, administrative or other error, and/or intentional misrepresentation.

The lack of written, formal procedures explaining how the Government calculates its 340B ceiling prices increases the possibility of differences in interpretation that could cause manufacturers' ceiling prices to differ. It is also possible for a manufacturer to correctly interpret the calculation but to make an administrative error in applying or transmitting the calculation. Alternatively, manufacturers can benefit from any overpayments that result from their intentional inflation of the 340B ceiling prices or the inappropriate manipulation, to their advantage, of any of the drug pricing data used in the calculation. OIG's current work will attempt to ascertain the extent to which each of these factors may be contributing to 340B entities paying more than the stipulated ceiling prices. A previous OIG report, "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities" (A-06-01-00060), found that five drug manufacturers inappropriately excluded certain sales from one of the drug pricing elements in the calculation, resulting in overcharges to 340B entities of $6.1 million in 1999.

BROADER PROGRAMMATIC ISSUES

Confidentiality Provisions

Confidentiality provisions in the Medicaid drug rebate provisions of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), regarding manufacturers' pricing information, impact HRSA's ability to ensure that 340B entities receive the appropriate ceiling price. The Medicaid drug rebate statute protects the pricing and other data that manufacturers

submit to CMS for the Medicaid drug rebate program, in particular Average Manufacturer Price (AMP) and Best Price, as confidential. The law states that the pricing information disclosed by manufacturers "...shall not be disclosed by the Secretary...in a form which discloses the identity of a specific manufacturer, ...[or] prices charged for drugs by such manufacturers," except as the Secretary determines to be necessary to carry out the provisions of the statute or in other limited situations.[1] This provision has been interpreted to mean that HRSA is precluded from revealing exact overcharges to 340B entities, so as not to reveal the 340B ceiling prices to the entities.

Confidentiality provisions related to disclosure of 340B ceiling prices also limit the ability of the Prime Vendor to negotiate for prices below stipulated 340B ceiling prices. The PHS Act mandates the creation of a Prime Vendor Program. The Prime Vendor may attempt to negotiate subceiling prices on behalf of 340B entities. However, the Prime Vendor cannot effectively negotiate subceiling prices if it is not allowed access to the 340B ceiling prices. Such access has been limited by the manner in which the confidentiality provisions have been interpreted.

340B Program Enforcement Authorities

We believe that HRSA lacks the necessary legislative, regulatory, and contractual authority to enforce manufacturer and wholesaler compliance with the PHS Act and the Agreement. The PHS Act does not provide HRSA with the authority to impose civil monetary penalties for noncompliance with the 340B program requirements. Instead, the PHS Act and the companion provisions of the Social Security Act require that manufacturers must comply with the terms of the 340B program and the Medicaid drug rebate statute. Noncompliance could result in termination from participation in the Medicaid and 340B programs. This remedy is so extreme that it limits the likelihood that it will be used. To date, it has never been used. Terminating a manufacturer's participation is an exceptionally severe sanction, given the effect that terminating a manufacturer would have on access to medications for the millions of Medicaid and 340B beneficiaries.

Further, it is CMS and not HRSA that initially receives the data from manufacturers, and manufacturers are not required to report the information directly to HRSA. HRSA does not have statutory authority to compel manufacturers to report complete drug pricing data in a timely matter to CMS. Under the Medicaid drug rebate program statute (pursuant to which manufacturers send data to CMS), the Secretary of HHS has the authority to impose a civil monetary penalty for late submission of drug pricing data. We are unaware of any use of this provision in recent years. Instead, manufacturers are generally notified by CMS of the late data and are afforded the opportunity to supply the previously missing data with a subsequent data submission. While subsequent data submissions do not pose a significant problem for the retrospective Medicaid drug rebate program, which CMS oversees, late submissions of the drug pricing data prevent HRSA's timely and

[1] 42 USC §1396r8(b)(3)(D)

accurate calculations of the Government's 340B ceiling prices. Also, because manufacturers are not required to share the 340B ceiling prices that they calculate with the Government, there are no data available for comparison.

OIG also found limitations with the obligations outlined in the Agreement. The Agreement gives the Secretary of HHS the ability to require manufacturers to reimburse entities for discounts withheld. However, even when HRSA attempts to take action against violators based on the Agreement, HRSA's lack of legal authority makes the Agreement challenging to enforce. For example, in response to the 2003 OIG finding that five manufacturers had overcharged 340B entities by $6.1 million, HRSA issued letters to each of the five drug companies requesting that they develop action plans that include refunding covered entities for overcharges. According to HRSA, the companies have responded to the letters, but refunds have yet to be recovered.

OIG found that the only compliance mechanism that HRSA currently has with regard to refunds is an informal dispute resolution process that has never been utilized. Because the 340B program dispute resolution process is voluntary, manufacturers and 340B entities are not required to participate. If the manufacturer does not cooperate with the dispute resolution process, HRSA can neither compel their participation nor sanction their lack of participation.

OIG RECOMMENDATIONS

OIG's recommendations to improve the 340B Program focus on the steps HRSA can take to strengthen its oversight and management of program operations and on the two broader programmatic issues I just described.

340B Program Oversight

To strengthen HRSA's ability to oversee the program, OIG recommends that HRSA: (1) publish detailed standards for the Government's calculation of 340B ceiling prices, (2) work with CMS to ensure timely receipt of manufacturers' pricing data, and (3) develop a strategic plan for managing the 340B program database. HRSA concurred with these recommendations and has made some progress in implementing them, including launching a new database to track entity participation.

In addition, OIG recommends that HRSA develop oversight mechanisms to verify that 340B ceiling prices are being correctly calculated by manufacturers. We suggest that HRSA selectively audit manufacturers and wholesalers. HRSA has stated its intention to review 340B prices that manufacturers voluntarily supply to them. However, OIG does not believe that this approach provides a sufficiently systematic review of compliance necessary to provide adequate oversight to the program.

OIG also recommends that HRSA develop monitoring mechanisms that allow for a comparison of the Government's 340B prices and the prices paid by 340B entities. There

are several ways HRSA could achieve this. For example, HRSA could spot-check covered entity invoices against the Government's record of 340B ceiling prices. Alternatively, HRSA could develop a system for covered entities to access certain secured pricing data to help them determine whether the prices they pay exceed the 340B ceiling prices.

Broader Programmatic Issues

OIG believes that permitting some disclosure of information about 340B ceiling prices is essential to improving the operation of the program. HRSA's options for using 340B ceiling prices to monitor the program are limited due to the confidentiality of the drug pricing data elements used to calculate the 340B ceiling prices. The Social Security Act expressly permits the Secretary to disclose information if disclosure is determined to be "necessary to carry out" the programs, including the 340B program. However, HRSA has been following a CMS interpretation of the confidentiality provision that prohibits HRSA from using the 340B ceiling prices to monitor the program. OIG sees a need for clarification of the confidentiality provision.

OIG also recommends that HRSA seek authority to establish penalties for program violations. We disagree with HRSA's assessment that it has sufficient authorities to enforce the requirements of the 340B program statute. The Secretary of HHS could terminate a manufacturer's participation in the Medicaid drug rebate and 340B programs, but HRSA has no effective penalties to use for violations of the PHS Act or the Pharmaceutical Pricing Agreement. We believe that legislation authorizing the imposition of penalties and fines would provide HRSA with more effective tools to enforce the 340B program requirements.

CONCLUSION

We appreciate the Committee's interest in this important subject. Further, we are encouraged by HRSA's response to our recommendations. We believe that HRSA has been responsive in terms of its improvements in the accurate calculation of the 340B ceiling prices and its 340B participant database. However, we encourage HRSA to fully address OIG's recommendations related to strengthening the administration and oversight of the 340B program. In addition, OIG continues to believe that confidentiality issues and a lack of enforcement authority impact HRSA's ability to ensure that the program is functioning properly and that 340B entities are paying at or below the 340B ceiling prices.

OIG is committed to continuing its review of this program and addressing the concerns of congressional oversight committees. As previously mentioned, OIG is currently engaged in a review to determine whether 340B entities pay at or below the statutorily-defined 340B ceiling price, and, if not, the potential reasons for price discrepancies. We anticipate a final report on this topic in Spring 2006. This concludes my testimony. I would be happy to answer your questions.