DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Washington, D.C. 20201

OCT 18 2005

The Honorable Charles E. Grassley
Chairman, Committee on Finance
United States Senate
Washington, DC 20510-6200

Dear Mr. Chairman,

I am writing in response to your letter dated September 1, 2005, in which you requested that the Office of Inspector General (OIG) compile a comprehensive list of its recommendations relevant to the administration of the 340B drug pricing program (340B Program), along with the date of each recommendation and OIG's knowledge of the status of each recommendation. You asked that OIG forward the list both to your Committee and to the Health Resources and Services Administration (HRSA).

Our response (enclosed at Tab A) is based on recommendations in three OIG reports that relate to issues outlined in separate letters that you sent to the Secretary of Health and Human Services and the HRSA Administrator and enclosed for our information. The reports are:

- *AIDS Drug Assistance Program Cost Containment Strategies.* OEI-05-99-00610. September 2000.

- *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities.* A-06-01-00060. March 2003.

- *Deficiencies in the 340B Drug Pricing Program's Database.* OEI-05-02-00071. June 2004.

In addition, our response includes a discussion of HRSA's progress on recommendations in a new final report we are issuing today entitled *Deficiencies in the Oversight of the 340B Drug Pricing Program.*[1] The new report (enclosed at Tab B) is part of OIG's continuing effort to address the concerns of congressional oversight committees, various Members of Congress, and the Department regarding this important program.

In general, HRSA has been reasonably responsive in terms of improvements to its 340B participant database and the accurate calculation of the 340B ceiling price. However, we do not believe that HRSA has fully addressed OIG's recommendations to strengthen the administration and effectiveness of the 340B Program. While the steps HRSA has stated it intends to take to monitor manufacturers' compliance with the 340B ceiling price formula and covered entities' compliance with the 340B Program are encouraging, they

[1] OEI-05-02-00072, October 2005.

do not go far enough to provide adequate oversight to the program. OIG continues to disagree with HRSA's assessment that it has sufficient authorities to enforce the requirements of the 340B statute. We continue to recommend that HRSA propose legislation that will authorize the imposition of appropriate penalties and fines to enforce the terms of the Public Health Services Act.

We appreciate your interest in our work and your encouragement to the Department to strengthen its management of this important program. If you would like to discuss this response, please contact me, or have your staff call Judy Holtz, Acting Director of External Affairs, at (202) 619-0260.

Sincerely,

Daniel R. Levinson

Daniel R. Levinson
Inspector General

Enclosures

cc:
The Honorable Michael Leavitt
The Honorable Elizabeth M. Duke

STATUS OF RECOMMENDATIONS BY THE OFFICE OF INSPECTOR GENERAL TO THE HEALTH RESOURCES AND SERVICES ADMINISTRATION RELATED TO THE 340B DRUG PRICING PROGRAM

OIG Report:
AIDS Drug Assistance Program Cost Containment Strategies
OEI-05-99-00610. September 2000.

Recommendation. HRSA should seek legislation to change the 340B ceiling price calculation to the Federal ceiling price calculation.

> OIG Knowledge of HRSA Action. OIG is unaware of any actions taken by HRSA to implement the recommendation.

Recommendation. HRSA should seek legislation to exempt all sales to 340B covered entities from the calculation of Non-Federal Average Manufacturers Price (Non-FAMP), to allow AIDS Drug Assistance Programs (ADAPs) to negotiate the lowest prices possible.

> OIG Knowledge of HRSA Action. HRSA successfully negotiated, with the Office of Veterans Affairs, an exemption from the Non-FAMP for all sub-ceiling price sales to 340B entities when the sub-ceiling price negotiation is conducted through HRSA's Prime Vendor. It is OIG's understanding that approximately 1,700 340B entities participate in the Prime Vendor Program, including approximately 600 disproportionate share hospitals, which command the largest volume of 340B purchases overall. If entities do not participate in the Prime Vendor Program, their sub-ceiling prices are not exempt from Non-FAMP.

Recommendation. HRSA should continue to work with rebate and non-participating ADAPs to devise ways to grant them access to upfront drug discounts. This includes allowing ADAPs that utilize a multiple contract pharmacy model for the purchase and distribution of pharmaceuticals to be eligible for the 340B Drug Pricing Program.

> OIG Knowledge of HRSA Action. In September 2000, HRSA instituted an "Alternative Method Demonstration Project" initiative that allows entities in the 340B Drug Pricing Program to apply to complete an approved time-limited demonstration project that can include contracting with multiple pharmacies. Prior to this initiative any 340B entity utilizing a multiple pharmacy model was prohibited from receiving the upfront 340B discount. Through the "Alternative Method Demonstration Project" initiative, five 340B entities with multiple pharmacies, none of which are ADAPs, can now achieve greater savings due to their access to the lower 340B ceiling prices.

Report:
Pharmaceutical Manufacturers Overcharged 340B-Covered Entities.
A-06-01-00060. March 2003.

Recommendation. HRSA should identify, for the five drug manufacturers identified in the report, the exact amount of the overcharges for each of the affected 340B covered entities and apply the overcharge amounts as offsets or credits to each entity's future purchases.

OIG Knowledge of HRSA Action. On September 21, 2004, the Associate Administrator, Healthcare Systems Bureau, sent letters to four pharmaceutical manufacturers who were identified in the report. (Five manufacturers were originally identified in the report; two have since merged.) The letters stated that it is necessary for each manufacturer to bring its pricing practices into compliance with section 340B of the Public Health Service Act. Manufacturers were asked to develop a corrective action plan to correct overcharges to 340B covered entities. Corrective action plans were to be delivered to the Office of Pharmacy Affairs (OPA) within 60 days after the manufacturers received the letter.

Two manufacturers responded that they had not calculated 340B prices improperly or overcharged covered entity customers. Both manufacturers cited guidance from the Centers for Medicaid and Medicare Services (CMS) as the basis of their price calculations. OPA reviewed the issue with CMS, and determined that both manufacturers calculated 340B prices improperly and must develop a corrective action plan to correct overcharges to covered entity customers. Letters have been drafted to the manufacturers stating this.

One manufacturer responded that it had been investigated by the U.S. Attorney's Office in Boston and OIG beginning in 2000 for its pricing practices. In 2003, the manufacturer entered into a settlement agreement with the Department of Justice (DOJ), U.S. Attorney's Office in Boston, and OIG. The manufacturer stated that it believed the matter to be resolved. OPA reviewed the settlement agreement with the Office of Counsel to the Inspector General (OCIG). It was determined that some of the conduct described in OIG's audit report was not covered by the settlement agreement. A letter has been drafted to the manufacturer stating this and requesting a corrective action plan to correct overcharges not covered by the settlement agreement and certification that the conduct described in OIG's report ceased after the settlement agreement.

The fourth manufacturer responded that it was currently under investigation by the US Attorney's Office in Boston. The manufacturer states that it will act appropriately with regard to 340B covered entity customers when the investigation is complete. OCIG has confirmed with DOJ that there is an ongoing investigation. DOJ has requested that HRSA not respond to the manufacturer at this time.

Report:
Deficiencies in the 340B Drug Pricing Program's Database
OEI-05-02-00071. June 2004

Recommendation. HRSA should develop a strategic plan to better manage the 340B Program data and improve the integrity of the database. We suggested that HRSA's plan include five elements:

1. A revalidation of all current information in the database;
2. An annual recertification process for entities participating in the discount program;
3. A separate listing of newly added or deleted entities;
4. A standard reporting format for entities' addresses, which includes appropriate "ship to/bill to" arrangements and does not include post office boxes; and
5. An additional field to designate entities with contracted pharmacy arrangements.

OIG Knowledge of HRSA Action. In general, HRSA has committed to improving the integrity of the 340B covered entities database, but continues to mention the impact budgetary limitations have on the agency's ability to commit to a timetable for full implementation of our recommendation. HRSA officially launched a new database on August 15, 2005.

In response to our first suggestion, HRSA has begun its first steps toward revalidating the information in the covered entities database. It started with those specific entity types that require annual recertification, such as tuberculosis clinics and sexually transmitted disease clinics, and annually update the information as a condition of their grant. HRSA has also taken action on revalidating the information for the 85 family planning clinics that receive grants from and HRSA's Office of Population Affairs. Finally, HRSA has removed over 1,000 entries that were duplicates or administratively inaccurate entries from the covered entities database.

HRSA has yet to revalidate all of the current information in the covered entities database. OIG has reason to believe that the database continues to contain a significant number of entities that do not actually participate in the 340B Program. We are not aware of any specific plans of action for ensuring that the entities that are listed in the database actively participate in the 340B Program or that the contact information is correct.

In response to our second suggestion, we are not aware of any actions taken by HRSA to require all enrolled entities to annually resubmit their 340B registration forms.

HRSA has, in response to our third suggestion, added information that identifies new and deleted entities through the "start" and "termination" participation date fields. These fields are now updated in real time rather than on a quarterly basis. HRSA has

also created an advanced query option that returns separate listings of entities that were added or deleted. Finally, users can link to a separate Excel spreadsheet that lists entities deleted from the database during revalidation efforts because the entities never participated in the program and should not have originally been entered.

In response to our fourth suggestion, HRSA's database now clearly identifies appropriate "ship to/bill to" arrangements and links together associated providers in a "related entities" section to improve the transmission of information to manufacturers. However, OIG is not aware of action by HRSA to review and replace post office box only entries.

Finally, in response to our fifth point, HRSA's new database now contains information on contract pharmacy arrangements, including all of the pertinent contact information for both the participating entity and its contracted pharmacy.

Report:
Deficiencies in the Oversight of the 340B Drug Pricing Program
OEI-05-02-00072. October 2005.

Recommendation. CMS and HRSA should work together to ensure accurate and timely pricing data for the Government's official record of 340B ceiling prices.

OIG Knowledge of HRSA Action. HRSA and CMS concurred with our recommendation. They signed a new Intra-Agency Agreement on September 20, 2005, effective for fiscal year 2005. HRSA did not previously have access to the 340B ceiling price data maintained by CMS for almost a year prior to this Agreement. As OIG is currently aware, under the terms of the new Intra-Agency Agreement, CMS will provide HRSA with the retroactive pricing data necessary to calculate the ceiling price. HRSA will receive from CMS only the elements necessary to calculate the ceiling price, but not the calculated 340B ceiling price that CMS previously supplied. HRSA will be responsible for calculating the Government's official 340B ceiling price.

Both agencies commented that they would continue to work together on issues relating to the acquisition of timely data from manufacturers and the resolution of problems with missing data; however, neither agency elaborated on specific outcomes accomplished thus far.

No Intra-Agency Agreement has been signed for fiscal year 2006. CMS and HRSA have until December 2005 to negotiate a new Intra-Agency Agreement for fiscal year 2006 to avoid an interruption in the calculation of the 340B ceiling prices used to monitor the program.

Recommendation. HRSA should establish detailed standards for the calculation of 340B ceiling prices.

OIG Knowledge of HRSA Action. According to agency comments, HRSA anticipates publishing detailed standards for the calculation of 340B ceiling prices on HRSA's Office of Pharmacy Affairs Web site. While we encourage such action, HRSA did not indicate an approximate timeline for posting this information or provide details regarding what these standards will cover.

Recommendation. HRSA should institute oversight mechanisms to validate its 340B price calculations and the prices charged to participating entities. OIG suggested that HRSA take three actions:

1. Compare the Government's official 340B ceiling prices to the manufacturers' ceiling prices each quarter to detect discrepancies;
2. Spot-check covered entity invoices against ceiling price data to ensure that entities are charged at or below 340B ceiling prices; and
3. Selectively audit manufacturers, wholesalers, and covered entities to ensure the integrity of the discount program.

OIG Knowledge of HRSA Action. To ensure the accuracy of the Government's calculation of 340B prices, HRSA has hired a contractor to develop a database to house the pricing data received from CMS and calculate 340B ceiling prices. Based on conversations with HRSA staff, we understand that the agency intends to create automatic edits of ceiling price calculations to ensure accuracy.

To validate the prices charged to 340B entities, HRSA has stated that it intends to compare manufacturers' pricing information, currently supplied on a voluntary basis, to its calculation of the official ceiling price. HRSA also stated its intent to review manufacturers' pricing data that major wholesalers provide to HRSA's Prime Vendor Program. Discrepancies in these comparisons will be promptly investigated and resolved, to the extent that resources permit. OIG believes that while these may serve as useful quality assurance checks for the agency as it assumes the new responsibility of calculating 340B ceiling prices, they do not provide a systematic review of compliance necessary to provide adequate oversight to the program.

In response to our suggestion to spot-check covered entity invoices against ceiling price data, HRSA concurred with the utility of such an exercise. However, HRSA stated that because it does not have the authority to require 340B participants to submit their invoices for review, then it will request the information on a voluntary basis for spot-checks. Because 340B participants do not have access to the ceiling prices to verify the accuracy of their charges, it is our belief that the participants would respond favorably to such a check. One concern not addressed is whether HRSA will share the results of comparisons with the entities, given the confidentiality concerns.

HRSA proposed that our third suggestion, to selectively audit manufacturers, wholesalers, and covered entities, be deferred to OIG. While OIG is committed to

ensuring the integrity of the 340B Program, as with all of the Department's programs, our recommendation is that HRSA increase its oversight of its program. We believe that this type of program monitoring is better maintained at the agency.

Recommendation. HRSA should seek authority to establish penalties for PHS Act violations.

OIG Knowledge of HRSA Action. In its comments to our report, HRSA expressed its desire to acquire experience with the changes that it plans to make with the administration of the 340B Program before legislation is proposed. HRSA did note, however, that a bill has been introduced in Congress (S.4) that would authorize HRSA to provide audits of the program.

In its September 14, 2004, response to the Committee, HRSA stated that it believes that existing authorities and processes provide adequate tools to enforce the requirements of the 340B Program. However, OIG asserts that existing remedies are insufficient. One potential remedy would be to terminate a manufacturer from the 340B Program, thereby making the manufacturer's products ineligible for reimbursement under the Medicaid program. Given the severity of this remedy, it will likely be invoked in only the most egregious of circumstances. Another potential mechanism to enforce 340B Program requirements is through a dispute resolution process. However, the current dispute resolution process is designed to address limited problems and has never been utilized. We assert that legislation authorizing the imposition of penalties and fines would provide HRSA with more effective tools to enforce the 340B Program requirements.

Recommendation. HRSA should provide participating entities with secure access to certain pricing data to help approximate 340B ceiling prices. HRSA could design a mechanism that allows participating entities to assess whether prices exceed the ceiling price. HRSA could also reinstate the publication of HRSA's Prime Vendor Program's selling price list on the agency Web site so covered entities can estimate accurate prices.

OIG knowledge of HRSA Action. HRSA has expressed its desire to supply the 340B ceiling price data, while protecting confidential pricing data, to participating entities. HRSA stated that it feels this is a reasonable idea and will explore its policy options to provide pricing information to entities. We are aware that HRSA, together with its Prime Vendor, has negotiated an agreement with at least one major manufacturer to receive and make available 340B ceiling prices to those entities that participate in HRSA's Prime Vendor Program. HRSA sees this as a "first step" with which it will test these ideas.

HRSA does not concur with our suggestion to reinstate the Prime Vendor Program's selling prices to its Web site and is exploring other options. We also

understand that HRSA's options are limited because CMS objects to sharing such information due to the confidentiality of the data elements used to calculate the ceiling price.