DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

OCT 21 2011

The Honorable Charles E. Grassley
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Senator Grassley:

Thank you for your letter requesting information on the Health Resources and Services Administration's (HRSA) actions to oversee the administration and effectiveness of the 340B Drug Pricing Program (340B Program).

HRSA is committed to program integrity and ensuring that 340B eligible entities and participating manufacturers are in full compliance with the 340B statute. Answers to your questions are provided as an enclosure to this letter.

We appreciate your interest in the 340B Program. Identical letters have been sent to Representative Upton and Senator Hatch.

Sincerely,

Mary Wakefield

Mary K. Wakefield, Ph.D., R.N.
Administrator

Enclosure

HRSA Responses to 340B Questions from
Senator Grassley, Senator Hatch and Representative Upton

1. ***Provide a detailed description of HRSA's past efforts and future plans to conduct oversight of the 340B program.***

Response: The Health Resources and Services Administration (HRSA), which administers the 340B Drug Discount Program (340B Program), conducts oversight of enrolled 340B covered entities and manufacturers participating in the program to ensure they are following legislative requirements. Oversight is based on statutory requirements, published guidance and program procedures.

Oversight of 340B Program participants focuses primarily on: (1) safety-net providers' eligibility for the 340B Program; (2) accountability for the use of 340B drugs only in the outpatient setting and for safety-net provider patients; and (3) avoidance of duplicate discounts. Oversight of manufacturers focuses primarily on: (1) required participation in the program; (2) the correct pricing of 340B drugs; and (3) providing equal access to purchase drugs at or below the 340B ceiling prices. Below is a summary of current and future activities.

Eligible Safety-Net Providers

- Eligibility Oversight:
    - HRSA determines eligibility and updates the federal list of participating 340B covered entities and contract pharmacies quarterly. We contact other federal agencies, including the Centers for Medicare and Medicaid Services (CMS), Centers for Disease Control and Prevention (CDC), and Indian Health Service (IHS) to confirm eligibility and grant status and coordinate programs.
    - HRSA follows its published guidelines regarding general covered entity enrollment. (See 58 Fed. Reg. 27289 (May 7, 1993) and 59 Fed. Reg. 25110 (May 13, 1994)).
    - HRSA maintains a public database that includes eligible participating covered entities and manufacturers. The 340B Database provides details about the approximately 16,900 entity sites, 8,000 contract pharmacy arrangements, and approximately 600 manufacturers participating in the 340B Program. As of July 1, 2011, all safety-net providers are now able to apply online to participate in the 340B Program. HRSA has made improvements to, and continues to modernize, the 340B database.
    - As of August 2011, HRSA is conducting annual recertification for all 340B covered entities. Prior to this date, HRSA recertified only certain entities annually (*e.g.*, STD, TB, HIV/AIDS grantees), as expressly required under section 340B (a)(7) of the Public Health Service Act (42 U.S.C. 256b).
    - HRSA monitors participating hospitals' disproportionate share (DSH) percentages quarterly. If a hospital no longer meets the required percentage, an inquiry is made. If the hospital is unable to produce evidence that it meets the requirement, it is removed from the 340B Program.

- HRSA monitors federally qualified health center (FQHC) grant status on a quarterly basis by verifying that the organization maintains its FQHC status.
- HRSA verifies the proprietary status of participating hospitals quarterly by matching the list of participating hospitals with CMS's list of hospitals to ensure that ineligible private for-profit hospitals are not participating in the 340B Program. Details on the process are provided in HRSA's response to Question 2, below.
- HRSA provides education to eligible safety-net providers on enrollment in the program. Details on this process are provided in HRSA's response to Question 2, below.

- Restriction of 340B drugs to outpatient settings, safety-net provider patients, and within the scope of a grant

  - HRSA follows its published 1996 guidance on the definition of a patient (61 Fed. Reg. 55156 (October 24, 1996)) and the restriction of 340B drugs to outpatient settings. In addition, the 1996 guidance states that entities that qualify for the 340B Program as a result of their federal grant are only allowed to use 340B drugs in a manner consistent with the scope of that grant.
  - HRSA investigates all reported cases of alleged drug diversion to non-patients or of drugs allegedly being used in an inpatient setting. HRSA refers cases to HHS's Inspector General (IG) or the Department of Justice (DOJ), when necessary, and works closely with them in further investigation. This process is described in detail in the response to Question 3, below.
  - A new mandatory administrative dispute resolution (ADR) process regulation is being developed to reflect recent legislative changes. An advanced notice of proposed rulemaking (ANPRM) on ADR was published in the Federal Register 75 Fed. Reg. 57223 (September 20, 2010). The comment period for the ANPRM closed on November 19, 2010, and HRSA is using the comments to draft a Notice of Proposed Rulemaking. As proposed in the President's FY 2012 Budget, user fees would be used to undertake the ADR process.
  - HRSA provides ongoing technical assistance (TA) and education to safety-net providers on 340B requirements and policies, through activities including:
    - Maintenance of the 340B website, which contains detailed, extensive educational material on requirements for 340B Program participation and adherence to program policies.
    - Operation of a call center by the HRSA Pharmacy Services Support Center (PSSC), a contractor, to provide consistent and reliable information about the 340B Program. This call center has offered over 17,000 unique encounters, which includes 7,300 stakeholders, in the last 5 years.
    - Maintenance of Pharmacy Technical Assistance services ("PharmTA")—where over 20 experienced pharmacists and health professionals trained on the 340B program provide assistance regarding 340B eligibility, registration, recertification, the HRSA database, 340B policy, billing, and guidelines.

        - Development of tools to assist safety-net providers in implementation and optimization of the 340B Program. There are currently over 30 tools including financial spreadsheets, action plans, informational/historical materials, and web-based forms that address the common and unique needs of safety-net providers and promote program integrity.
    - HRSA developed a Peer-to-Peer program to provide technical assistance using a collaborative model. The Peer-to-Peer program has 11 high-performing 340B sites that HRSA selected based on a rigorous assessment to highlight during webinars and other educational events. Since its inaugural session in June 2011, participation in the Peer-to-Peer webinars has grown to 200 registrants per session. The nine webinars scheduled will allow covered entities the opportunity to share operational knowledge in a collaborative learning environment. HRSA participates in all webinars to ensure accurate information is conveyed. This model has allowed HRSA to reach more safety-net providers using a cost-effective approach, and it will continue to grow.
    - Over the last two years, HRSA has presented at over 30 conferences and webinars/teleconferences to provide 340B education to various stakeholders.
    - In the last five years, HRSA has participated in over 120 speaking/educational opportunities at various local, state, and national 340B stakeholder meetings, conferences, and webinars where HRSA and its contractors have presented on 340B eligibility requirements, compliance requirements for covered entities and manufacturers and 340B Program optimization.

- Avoidance of Duplicate Discounts:

    - HRSA maintains the Medicaid Exclusion File to prevent duplicate discounts with Medicaid. Under the mechanism established through section 340B(a)(5) of the Public Health Service Act (PHSA), covered entities are required to inform HRSA (by providing their Medicaid billing number) at the time they enroll in the 340B Program whether or not they plan to bill Medicaid for covered outpatient drugs dispensed to Medicaid beneficiaries. If an eligible entity plans to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid, the covered entity must notify HRSA in order to prevent a duplicate discount. Guidance for the Medicaid Exclusion File is outlined in the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Duplicate Discounts and Rebates on Drug Purchases, which was published at 58 Fed. Reg. 30458 (June 23, 1993). This process is discussed in detail under HRSA's response to Question 5, below.
    - States have been advised by HRSA and CMS to consult this Medicaid Exclusion File to avoid duplicate discounts. CMS also has established a process for resolving disputes between manufacturers and states on duplicate discounts. The process can be found at: https://www.cms.gov/MedicaidDrugRebateDispR/Downloads/340BRelatedDisputes.pdf .

- Manufacturers use the Medicaid Exclusion File as the official data source to prevent duplicate discounts between 340B and Medicaid.
- HRSA works with OIG, DOJ, and Medicaid state fraud programs to investigate suspected violations of 340B by safety-net providers.
- In collaboration with CMS, HRSA is planning a webinar for state Medicaid agencies and other 340B stakeholders regarding the Medicaid Exclusion File in November 2011.

Manufacturers

- Participation in the Program:

  - Manufacturers who participate in the Medicaid drug rebate program are required to participate in the 340B Program. In order to participate in the 340B Program, manufacturers must sign a Pharmaceutical Pricing Agreement (PPA) with the Secretary under which the manufacturer agrees to charge a price that will not exceed the amount determined under a statutory formula when selling covered outpatient drugs to particular covered entities listed in the statute. No manufacturer required to participate has refused to participate in the 340B Program. A limited number of manufacturers voluntarily participate in 340B, but not in Medicaid.
  - HRSA reviews quarterly the list of manufacturers participating in the Medicaid drug rebate program to ensure they are also participating in the 340B Program. If a manufacturer has not signed the PPA, HRSA contacts the manufacturer and requests it to execute and submit the PPA to HRSA. HRSA has executed PPAs with over 600 pharmaceutical firms. New agreements are processed as they are received.
  - HRSA publishes a list of all manufacturers participating in the 340B Program on the HRSA database that is accessible to the public. This process is provided in detail under HRSA's response to Question 3, below.

- Correct Pricing of 340B Drugs:

  - HRSA calculates 340B drug prices quarterly for 26,000 drugs. HRSA has an interagency agreement with CMS that provides two of the components of the 340B ceiling price computation—the average manufacturer price and the unit rebate amount. HRSA calculates ceiling prices based on this information and has a proprietary pricing database for 340B prices. HRSA also obtains data on a quarterly basis from First Databank to calculate 340B ceiling prices that include unit of measure and package size to improve the accuracy of the 340B price.
  - Currently, when an entity believes it has been charged an incorrect price, it contacts HRSA, which will investigate and determine whether the correct pricing was applied and then notify the entity or the manufacturer, as appropriate. Due to new statutory authority, HRSA now will be establishing a secure pricing web site accessible to all 340B covered entities, providing pricing transparency to all participating entities. It will be password

protected. When implemented, covered entities will be able to determine whether they have been correctly charged without contacting HRSA. Funds from the proposed user fee would be used to construct the data base as stated in the President's FY 2012 Budget.

- Once developed, HRSA will also use the mandatory ADR process, as noted above, to handle unresolved pricing disputes.
- By statute, HRSA has established a 340B Prime Vendor Program (PVP) to obtain additional drug and other medical supply savings for 340B covered entities and to assist with navigating pricing information. In addition, the PVP:
  - Provides participating covered entities with quarterly pricing and savings opportunity reports to assist in managing drug formularies and lowering drug expenditures. Reports are available to assist covered entities with identifying best buys each quarter, and custom reports on additional savings opportunities.
  - Negotiates sub-340B pricing through contract negotiations and/or competitive bid processes. These sub-ceiling prices are available to covered entities via a secure website. This process provides pricing transparency for participating covered entities. The PVP has successfully negotiated sub-340B pricing for over 3,500 pharmaceuticals delivering an additional $46 million in value for safety-net providers in the 340B Program.
  - Provides access to the three national wholesalers' 340B pricing files to assist with pricing validation. The price file is made available via the PVP secure website. If a safety-net provider has additional questions regarding pricing, they can contact HRSA or the PVP to verify 340B pricing.

- <u>Providing Equal Access to Drugs for 340B Covered Entities</u>:

  - As indicated in HRSA's guidance, a manufacturer may not impose prior conditions on the offer of 340B discounts to a covered entity.
  - HRSA's policy states that manufacturers may develop alternate allocation procedures when sufficient supply of a covered drug is not adequate to meet market demands. These allocation procedures must demonstrate that 340B providers are treated the same as non-340B providers. In order to ensure alternate allocation procedures meet these guidelines, manufacturers must notify HRSA's Office of Pharmacy Affairs (OPA) in writing. Once these procedures are approved, OPA will notify manufacturers of OPA's decision and publish them on the OPA website. HRSA plans to release a policy notice about allocation procedures to this effect.
  - When HRSA is notified that a manufacturer is not providing equal access for 340B covered entities, HRSA contacts the manufacturer to attempt to negotiate an appropriate solution. When this negotiation does not resolve the issue, HRSA refers the case to the DOJ for compliance action.

In addition to this general overview, please include the following information:

a. ***A breakdown of the number and type of audits performed by HRSA with respect to the 340B program since 1992. Please provide the protocols, results, and subsequent corrective action plans for each.***

Response: HRSA has worked closely with other government agencies to conduct program audits. Two such audits of covered entities included an OIG audit of the Mashantucket Pequot Tribe in 2000 and a DOJ audit of the Aliquippa Community Hospital in 2005. Both audits were conducted after HRSA staff engaged the safety-net providers and failed to reach a satisfactory response. Both cases resulted in "cease and desist" letters and the removal of the safety-net providers from the list of entities eligible to participate in the 340B Program and, in the case of Aliquippa, a federal indictment and trial of a physician. HRSA has not independently carried out audits of 340B covered entities or participating manufacturers to date. However, as recommended by the Government Accountability Office (GAO) in a September 2011 report (GAO-11-836), HRSA is planning additional audits of covered entities for FY 2012. Details on this process are provided below.

b. ***Copies of protocols and any strategic planning documents related to future audits of the 340B program planned by HRSA and/or its contractors or partners.***

Response: In accordance with the recommendations in the GAO report referenced above, HRSA plans to conduct selected audits of participating covered entities beginning in FY2012. HRSA will be using existing published 340B guidance available at http://www.hrsa.gov/opa/federalregister.htm as a guideline. For the scope of auditing plans and auditing protocols, HRSA will specifically use the existing 340B audit guidelines as published in December 12, 1996 (61 Fed. Reg. 65406), available at ftp://ftp.hrsa.gov/bphc/pdf/opa/FR12121996.htm. Attached is a preliminary FY2012 340B Audit Schedule that HRSA will be implementing, subject to funding availability. HRSA will continue its partnerships with the OIG, DOJ, and state Medicaid programs to identify further investigations and additional oversight needed to improve the integrity of the 340B Program. In addition, HRSA is working closely with its Division of Financial Integrity to incorporate 340B Program compliance requirements into the federal grantee audit standards (A-133). Manufacturers also have the authority to audit. HRSA has already met with and continues to meet with and encourage manufacturers to send audit work plans to HRSA. HRSA plans to issue a letter to manufacturers, which will be publicly available on its website, encouraging manufacturers to submit audit plans to HRSA to investigate claims of diversion and duplicate discounts as outlined in the 340B audit guidelines.

2. ***Describe in detail the process by which HRSA verifies eligibility of both covered entities and drug manufacturers for participation in the 340B program. Please include the frequency of such eligibility verification processes.***

Response:

Covered Entity Eligibility

- The safety-net providers eligible for the 340B Program are set forth in section 340B(a) of the PHSA. Participation is voluntary, and eligibility does not mean automatic entry into the program. A safety-net provider must first notify HRSA of its intention to participate by registering for the 340B Program. Each safety-net provider must submit the necessary information to HRSA to enroll in the 340B Program so HRSA can review its information and verify that all criteria are met. HRSA's published guidelines regarding general covered entity enrollment are available at 58 Fed. Reg. 27289 (May 7, 1993) and 59 Fed. Reg. 25110 (May 13, 1994).
- Online registration is available, and enrollment into the program is conducted on a quarterly basis as set forth in guidelines. The normal quarterly deadlines for submitting a 340B Program registration to HRSA are a month before the start date in the 340B Program. The quarterly deadlines for registration submission to HRSA are December 1 for the quarter beginning January 1; March 1 for the quarter beginning April 1; June 1 for the quarter beginning July 1; and September 1 for the quarter beginning October 1. Participation in the 340B Program normally begins on the first day of a quarter, except in the cases of a Secretarial declared public health emergency in which HRSA enrolls safety-net providers in the geographic area where the emergency has been declared on a rolling basis (*i.e.*, as submissions are received and verified by HRSA).
- Details regarding eligibility requirements are on the HRSA website at www.hrsa.gov/opa. There are currently over 20 entity types eligible for the 340B Program, with each having a unique set of criteria that makes them eligible. HRSA also provides technical assistance to assist safety-net providers in making their decision on whether to enroll, how to enroll, how to ensure compliance, and how to optimize the 340B Program. Verification procedures used by HRSA vary by entity type:
    - If the entity is a federal grantee, HRSA works with the HRSA bureaus/offices and the other HHS federal agencies responsible for administering those grants (*e.g.*, CDC for STD/TB clinics, IHS for eligible tribal clinics) to verify the grant status, scope of the grant, and site location/physical address of the enrollee prior to approval.
    - For hospitals, the following verification activities are conducted:
        - Verification that the hospital meets the three statutory requirements outlined in section 340B(a)(4)(L)(i) of the PHSA for participation in the 340B program: (1) non-profit status is verified by submitted IRS documentation; (2) DSH eligibility, if applicable, is provided by CMS and verified by the most recently filed Medicare-cost report; and (3) private hospitals must have a contract with state or local governments to provide health care services to low income individuals who are not

entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the state plan of Title XIX of the Social Security Act. As part of the registration process, the hospital must submit a form that attests to the aforementioned statement that is signed by both an authorized public official and a hospital executive. HRSA provides hospitals a list of recommendations during the enrollment process that can be used in developing a contract between a state and the hospital.

- Depending on the type of hospital, if appropriate, other information may be required such as:
    - Facility licensure;
    - Proprietary status of hospital-public, non-profit or private; and
    - Group purchasing organization (GPO) participation.
- Verification of the Medicare cost report information to ensure outpatient clinics are eligible as outlined in the September 1994 final guidance (59 Fed. Reg. 47884). For outpatient clinics, the following documents are required and reviewed:
    - Worksheet A from the most recently filed cost report. If the clinics are bundled on the worksheet (i.e. not individually listed by name), the entity must provide supplemental documentation.
    - Worksheet S-2 from the most recently filed cost report for clinics with a different Medicare number from the main hospital.
    - Worksheet E part A from the most recently filed cost report for hospitals with a DSH adjustment percentage requirement.
    - In cases where the name of the clinic is not the same as the cost reporting listing, documentation that shows that the outpatient clinic was filed with the most recent cost report.

- All safety-net providers are required to inform HRSA (by providing their Medicaid billing number) at the time they enroll in the 340B Program whether they plan to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid. HRSA maintains this list known as the "Medicaid Exclusion File" on HRSA's public website to inform states and manufacturers that rebates should not be obtained and are not due on drugs billed to Medicaid under those numbers. HRSA provides guidance to covered entities and states on how to use the Medicaid Exclusion File on the HRSA website in its "Medicaid Exclusion Tutorial" and "Medicaid Exclusion File Basics" (http://www.hrsa.gov/opa/medicaidexclusion.htm). Guidance for the Medicaid Exclusion File is outlined in a Federal Register notice. (Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Duplicate Discounts and Rebates on Drug Purchases published at 58 Fed. Reg. 34058 (June 23, 1993)).
- Once a safety-net provider is verified as eligible and is listed on the HRSA public database, it can then purchase drugs under the 340B Program as a 340B covered entity. It is the responsibility of each covered entity to contact HRSA with any changes or updates to its existing profile while it is participating in the 340B

Program. This guidance to covered entities is outlined on the HRSA website and is also communicated to entities via email upon enrollment. For additional discussion regarding eligibility oversight, see response to Question 1, above.

- Covered entities have the ability to contract with a pharmacy or pharmacies to provide pharmacy services to their patients as outlined in the March 2010 guidance (75 Fed. Reg. 10272 (March 5, 2010)). To ensure that drug manufacturers and drug wholesalers recognize contract pharmacy arrangements, covered entities that elect to utilize a contract pharmacy or pharmacies are required to submit an enrollment form to HRSA who then reviews and verifies information submitted prior to including the contract pharmacy on the HRSA public database. The covered entity is responsible and accountable for compliance with all requirements to prevent diversion of covered drugs to individuals other than patients of the covered entity. See response to Question 1, above, regarding accountability for the use of 340B drugs only in the outpatient setting and for safety-net provider patients. The covered entity and the contract pharmacy must agree that they will not resell or transfer a 340B drug to any party but the covered entity's patients, and both parties must also establish an arrangement with the state Medicaid agency to prevent duplicate discounts. As outlined in HRSA guidelines, auditable records must be maintained and available upon HRSA's request.

Manufacturer Participation

- Manufacturers who participate in the Medicaid drug rebate program are required to participate in the 340B Program. In order to participate in the 340B Program, manufacturers must enter into an agreement with the Secretary under which the manufacturer must agree to charge a price that will not exceed the amount determined under a statutory formula when selling covered outpatient drugs to particular covered entities listed in the statute. This agreement is known as the Pharmaceutical Pricing Agreement (PPA). Signing the PPA does not prohibit a manufacturer from charging a price for a covered outpatient drug that is lower than the 340B ceiling price. That agreement with instructions can be found at ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf .
- HRSA has written Standard Operating Procedures for processing PPAs. PPAs are processed and reviewed for accuracy as they are received. HRSA verifies the labeler code for which that PPA represents using FDA data. Once determined acceptable, HRSA signs the agreement which is then mailed back to the manufacturer and entered onto the HRSA public 340B database. A manufacturer is required to notify HRSA of any changes in the PPA agreement, including personnel or inventory so the information can be updated.
- On a quarterly basis, HRSA reviews CMS data to determine manufacturer participation in Medicaid. If a manufacturer is on the Medicaid list, but does not have a signed PPA with HRSA, the manufacturer is contacted by HRSA to complete this agreement.

3. ***Describe in detail the process by which HRSA performs ongoing compliance oversight of covered entities and drug manufacturers after they are approved for participation in the 340B program. Please include the frequency of such compliance processes.***

Response:

Covered Entities

- Prior to 2010, HRSA was required to annually recertify certain covered entities (e.g., STD, TB, HIV/AIDS), under section 340B(a)(7) of the PHSA (42 U.S.C. 256b). HRSA worked with various federal programs to verify eligibility of participating 340B federal grantees during the recertification process. Since 2006, approximately 400 sites per year have been removed as part of annual recertification. The recertification process, in general, includes verification of grant status, updating contact information, verification of all eligibility requirements as defined by statute, updating of the entity's intention to bill Medicaid, and when applicable, GPO exclusion attestation.
- HRSA is now statutorily required to annually recertify all 340B covered entities. As of August 2011, HRSA has initiated a phased approach to recertification. This recertification process will enable HRSA to verify that all covered entities continue to meet the statutory requirements for program participation. All Ryan White grantee programs were completed as of October 1; over 300 sites were verified and 13 sites were removed from the program because they no longer met eligibility criteria. The STD/TB grantee recertification began on October 1, and will be followed by Indian Health Service clinics in November, and hospitals in February 2012. Even though HRSA is conducting this recertification annually, covered entities continue to be responsible for informing HRSA of any changes or updates to their existing profiles throughout their participation. Since 2006, HRSA has removed an additional 500 sites that have self-reported they no longer meet the 340B Program eligibility criteria.
- Each quarter, HRSA verifies the proprietary status of participating hospitals by matching its list of participating hospitals with CMS's list of hospitals to ensure that ineligible private, for-profit hospitals are not participating. Before terminating the hospital from the 340B Program, HRSA confirms the accuracy of this information.
- Each quarter, HRSA monitors DSH percentages. Hospitals are subsequently removed from the program if they fall below the DSH percentage for eligibility. Over the last year, HRSA removed approximately 80 DSH hospital sites that no longer met the requirements.
- Each quarter, HRSA monitors FQHC status to ensure organizations are still eligible to participate in the 340B Program.
- Oversight of the 340B Program includes ongoing review of information coming from covered entities, manufacturers, stakeholders, the Pharmacy Services Support Center and Prime Vendor (HRSA contractors), and other information sources. HRSA investigates all cases of alleged diversion that are reported to the Program. There are two types of situations that result in initiation of an investigation.
    - When a stakeholder reports general concerns or issues to HRSA that may signify inappropriate use of 340B drugs or simply a change in prescribing or patient load, HRSA conducts additional fact finding to determine whether a

program violation is occurring. In these types of cases, HRSA first encourages the safety-net providers and manufacturers to work through the issue to better understand the practices in place to ensure diversion is not occurring. HRSA is developing a system to maintain an ongoing record of the investigation and resolution of these types of cases. HRSA estimates that it receives and resolves 10 to 20 inquiries of this type each year.

  - There are also more formal cases when fraud or diversion may exist. After receiving information to this effect, or after a formal audit, HRSA investigates and then refers these types of cases to the appropriate federal agency (*i.e.*, OIG, DOJ, or FBI) for further investigation. We have records on two cases of diversion in the program, and in both cases the covered entities were removed from 340B participation. In the past year, two additional cases have been referred to the OIG to determine whether further action on the case is warranted. HRSA is developing a plan for tracking the investigation and resolution of all alleged cases that have been referred.

- The 340B statute requires that covered entities maintain auditable records that demonstrate compliance with the prohibition against duplicate discounts. Under section 340B(a)(5)(D) of the PHSA, the Secretary also has the authority, after an audit, notice, and hearing, to find the covered entity liable to the manufacturer in an amount equal to the reduction in the price of the drug. Covered entities are required to inform HRSA how they plan to use 340B drugs for their Medicaid patients (by providing their Medicaid billing number) at the time they enroll in the 340B Program. Covered entities have the option of choosing to dispense non-340B purchased drugs to Medicaid patients, also referred to as the "carve out" option. The "carve out" option is often selected by covered entities if the state Medicaid dispensing fee for 340B drugs is inadequate to cover costs. Covered entities must notify HRSA if there are changes to this Medicaid billing practice throughout their participation as to whether they plan to purchase and dispense 340B drugs for their Medicaid patients and bill Medicaid. This information is also verified during annual recertification.

Manufacturers

- On a quarterly basis, HRSA reviews the CMS website to review manufacturer participation in Medicaid. If a manufacturer is on the Medicaid list, but does not have a signed PPA with HRSA, the manufacturer is contacted to complete this agreement.
- Under the 340B Program, the manufacturer must agree to charge a price that will not exceed the amount determined under a statutory formula when selling covered outpatient drugs to particular covered entities listed in the statute.
- In 2007, HRSA implemented a voluntary pilot project with a group of drug manufacturers to improve the integrity and transparency of 340B drug prices paid by participating safety-net clinics and hospitals. Manufacturers voluntarily participated in the pilot and provided drug pricing information in a consistent electronic format. HRSA worked with each manufacturer to resolve any price variances between the submitted prices and the program-calculated prices. The 340B Prime Vendor currently works with a sample group of approximately 20 manufacturers that provide the 340B Prime Vendor their calculated quarterly ceiling prices to post in a secure area of their website for access by participating covered entities. The participating

manufacturers have signed separate agreements with the 340B Prime Vendor, enabling them to post the ceiling pricing in the interest of improving pricing transparency and integrity. The pilot program and the 340B Prime Vendor's ongoing efforts with manufacturers will assist HRSA in implementing the recent legislative provisions that require HRSA to create a website which displays ceiling price information for entities.

General Oversight Activities

- New authorities provided to HRSA will assist in strengthening the existing HRSA program integrity functions. The FY 2012 President's budget proposes a user fee that would be used by HRSA to implement new program integrity provisions. Language in the President's FY 2012 proposed budget and the FY 2012 Senate Appropriations bill proposes a user fee of 0.1 percent that would be calculated on and added to the price of the 340B drug. Covered entities would have to pay the user fee to continue to participate in the 340B Program. The fee would be collected by the manufacturer (the manufacturer does not pay the fee) and submitted to the Treasury into an account that HRSA would use to operate the 340B Program and undertake program integrity activities. Activities to be implemented with the user fee would include, but would not be limited to:
    - Manufacturer Integrity (Civil Monetary Penalties (CMP) regulations)
    - Covered Entity Integrity (Guidance and/or regulations)
    - Pricing Changes and Transparency (Guidance and/or regulations and online access in 340B data system)
    - Administrative Dispute Resolution (Regulations)
    - Pricing system to allow access to 340B prices by covered entities & manufacturers (Data system)
- Patient Definition
    - HRSA is reviewing the patient definition guidance. If HRSA determines a new patient definition is needed, it would be published as a proposed guidance and/or a proposed regulation depending on the scope of the definition.
- Additional program integrity efforts consist of the following actions:
    - Conducting selected audits of participating covered entities annually. As outlined in Question 1, HRSA will be using existing published 340B guidance for auditing plans and auditing protocols to investigate 340B compliance and cases of diversion.
    - Planning to issue three policy letters to manufacturers, to be publicly available on the HRSA website, which address HRSA's non-discrimination guidance, penny pricing, and manufacturer audits.
    - Planning to issue a policy letter to all stakeholders, to be publicly available on the HRSA website, outlining in detail the hospital criteria for 340B eligibility.
    - In collaboration with CMS, HRSA is planning a webinar for state Medicaid agencies and other 340B stakeholders regarding the Medicaid Exclusion File and duplicate discounts for November.

4. ***For the past five fiscal years, please provide an itemized breakdown of all appropriations, obligations, and expenditures requested and received as part of HRSA's annual budget for funds dedicated to oversight of the 340B program including, but not limited to, covered entity verification and compliance among all program participants.***

Response:

	2007	2008	2009	2010	2011
340B Appropriated Funds (in millions)*	0	0	1.470	2.220	4.480
HRSA Program Funds (in millions)**	2.756	3.349	4.142	3.431	3.730
Affordable Care Act (ACA) Implementation Fund (in millions)***	0	0	0	1.584	0
Program Management Funds for Staff (in millions)	1	0.9	0.900	1.100	1.100
Number of Covered Entity Sites Participating	12,639	13,285	14,258	15,530	16,960
Number of Contract Pharmacy Arrangements	1,799	2,088	2,483	6,099	8,096

*The majority of HRSA 340B Program appropriated resources are used for program integrity and compliance.
**HRSA Program Funds are used for enrollment and technical assistance for HRSA covered entities such as Federally Qualified Community Health Centers, Ryan White Programs, Maternal and Child Bureau Hemophilia Treatment Centers, Critical Access Hospitals, and those overseen by the Indian Health Service and Centers for Disease Control and Prevention.
***The ACA Implementation Funds were used for activities as authorized by Section 7101 of the ACA, including new entity enrollment and technical assistance.

5. ***In a June 2011 Department of Health and Human Services' Office of Inspector General (OIG) report, the OIG reported that 14 states currently conduct postpay audits of covered entities who receive 340B-purchased drugs. Is HRSA aware of these audits? If yes, what processes does HRSA have in place to enforce Section 340B (5) to ensure that duplicate discounts are not provided?***

Response: HRSA has published guidelines in the Federal Register to inform covered entities and the states that state Medicaid policy governs covered entity participation in a state Medicaid program. In addition, HRSA has provided assistance to the states and manufacturers by providing historical information and clarifying data in the Medicaid Exclusion File to prevent duplicate discounts.

HRSA is aware that some states are auditing covered entities. HRSA is not involved in state Medicaid audits or other processes involving financial transactions between states and covered entities for overpayments.

HRSA has in place the following processes to enforce Section 340B(a)(5) regarding duplicate discounts:

- **Medicaid Exclusion File:** This file is part of the HRSA database (http://opanet.hrsa.gov/opa/MedicaidExclusionFiles.aspx) and maintains the Medicaid Provider Numbers/NPIs for entities that use 340B drugs for Medicaid patients. Medicaid programs use this file to identify Medicaid Provider Numbers/NPIs from 340B entities, and thus forego rebate requests from manufacturers on claims associated with those entities. The guidance associated with this mechanism may be found here: ftp://ftp.hrsa.gov/bphc/pdf/opa/FR06231993.htm

- **Medicaid Exclusion Tutorial:** This is an online resource of detailed instruction and information, designed to help entities and Medicaid programs properly use the Medicaid Exclusion File found at: http://www.hrsa.gov/opa/medicaidexclusion.htm

- Additional HRSA actions regarding duplicate discounts include hosting a webinar, in collaboration with CMS, for state Medicaid agencies and other 340B stakeholders regarding the Medicaid Exclusion File.

6. ***Describe in detail what processes HRSA has in place to work with the Centers for Medicare and Medicaid Services (CMS) to enforce Section 340B(5) of the statute regarding duplicate discounts?***

Response: HRSA and CMS have a strong working relationship through which both agencies communicate and assist each other in implementation of its respective statutory authorities. CMS has included the Medicaid Exclusion File and the Medicaid Exclusion Tutorial in the CMS "Dispute Resolution-Best Practice Suggestions for Resolving 340B-Related Disputes" and posting the document on the CMS web site. As recommended by OIG, CMS and HRSA will continue to work collaboratively to alert states when HRSA issues guidance relevant to the Medicaid program and CMS will instruct states to notify HRSA if they find discrepancies between their records and the Medicaid Exclusion File.

HRSA has plans with CMS to provide technical assistance including educational webinars and collaborative discussions with states. HRSA, in collaboration with CMS, is planning a webinar for November to provide state Medicaid agencies and other 340B stakeholders with technical assistance about the Medicaid Exclusion File and duplicate discounts.

7. ***Is HRSA notified of each dispute or payment discrepancy between covered entities and drug manufacturers? If a dispute is resolved, are the covered entity and manufacturer required to report such dispute and resolution? What action has HRSA taken to resolve future disputes based on lessons learned from past disputes?***

Response: On December 12, 1996, HRSA published the Manufacturer Audit Guidelines and Dispute Resolution Process for the 340B Program (61 Fed. Reg. 65406). That notice provided guidelines for disputes that may arise between covered entities and participating manufacturers regarding implementation of the provisions of section 340B. To resolve these disputes in an expeditious manner, HRSA developed a voluntary dispute resolution process through which program participants can request that HRSA review evidence of a suspected violation and the Agency then decides whether to initiate the process. HRSA, through this guidance, requires covered entities and manufacturers to work in good faith to implement their respective legal responsibilities prior to involving the Agency. HRSA is therefore not informed of each and every dispute or payment discrepancy. HRSA believes that many of these disputes are resolved privately. The parties are not required to report resolution of resolved disputes. Since 1996, only two disputes have been received by HRSA.

- In one instance, the administrative dispute resolution process was dismissed after the covered entity did not respond and the process was voluntary in nature. After notice and hearing procedures under section 340B(a)(5)(D) of the PHSA, the Secretary found the covered entity liable to the manufacturer after the determination was made that the covered entity had diverted 340B product in violation of section 340B(a)(5) of the PHSA. The covered entity was also removed from the 340B Program.
- The other instance was a dispute submitted by a manufacturer claiming a covered entity was diverting 340B drugs to non-patients. HRSA convened a dispute resolution committee pursuant to the guidelines. However, the covered entity disputed the manufacturer's assertion that there had been negotiation in good faith as required by the HRSA guidelines, and the parties continued to dispute whether there had been negotiation in good faith. Due to the voluntary nature of the process and the requirement of mutual good faith to proceed, the dispute was dismissed without prejudice. The manufacturer then appealed HRSA's dismissal, and HRSA decided to affirm the dismissal of the dispute. However, HRSA is currently investigating the situation under its own authority and will be communicating with the covered entity directly to investigate the alleged diversion.

HRSA has new authority to resolve disputes and is working to implement these provisions. This authority requires the HHS Secretary to establish and implement an administrative process through regulations for resolution of: (1) claims by covered entities that they have been overcharged for drugs purchased through the 340B Program; and (2) claims by manufacturers, after the conduct of audit as authorized by section 340B(a)(5)(C) of the PHSA, of violations of the prohibition of duplicate discounts or rebates and/or the prohibition on resale of drugs purchased under the 340B Program. HRSA published an Advanced Notice of Proposed Rulemaking (ANPRM) on September 20, 2010, to request comments from stakeholders regarding the implementation of this new process. HRSA is also using lessons learned from the voluntary process that has been in place since 1996 to promulgate

regulations. HRSA is currently reviewing the ANPRM comments and drafting a Notice of Proposed Rulemaking.

8. ***For the past five fiscal years, provide an itemized breakdown of the percentage and dollar amount of HRSA's annual budget that goes towards covered entity outreach, including, but not limited to, HRSA officials' participation in conferences, seminars, or events with covered entities.***

Response: The chart below represents the portion of the appropriated funds and staff dollars used for direct covered entity outreach. HRSA has participated in national conferences, seminars, and other events sponsored by covered entities or pharmaceutical related organizations to provide accurate and complete education and information to currently and potentially participating covered entities and contract pharmacies. The focus is always on ways to utilize the program benefits while ensuring the entity adheres to program requirements. The Program has also conducted webinars on the basic 340B Program in addition to webinars on specific topic areas and maintains extensive questions and answers to address program issues. HRSA Program Funds are used for enrollment and technical assistance for all covered entities. The ACA Implementation Funds were used for activities as authorized by Section 7101of the ACA, including new entity enrollment and technical assistance.

	2007	**2008**	**2009**	**2010**	**2011**
340B Appropriated Funds (in millions)	0	0	1.470	2.220	4.480
HRSA Program Funds	2.756	3.349	4.142	3.431	3.730
ACA Implementation Fund (in millions)	0	0	0	1.584	0
Program Management Funds for Staff (in millions)	1.000	0.900	0.900	1.100	1.100
Total Funds	**3.756**	**4.249**	**6.512**	**8.335**	**9.310**
Non outreach funding**	0.967	0.637	2.288	3.121	4.594
Contractor Technical Assistance	2.496	3.281	3.828	4.251	4.419
Contractor Conferences	0.277	0.293	0.360	0.393	0.275
OPA Conferences	0.016	0.038	0.036	0.570	0.022
Appropriated Funds for Outreach	**2.789**	**3.612**	**4.224**	**5.214**	**4.716**
% of Appropriated Funds*	**74%**	**85%**	**65%**	**63%**	**51%**

*Percentage of Appropriated Funds calculated by the following:

Contractor Technical Assistance + Contractor Conferences + OPA Conferences
Divided by
340B Appropriated Funds + HRSA Program Funds + ACA Fund + Program Management Funds

**Non outreach funding is IT, salaries, outgoing interagency agreements, training, travel, supplies, and other supported activities.

Preliminary Audit Plan

Est. or Actual Date	Actions to be Taken	QTR1			QTR2		
		Oct	Nov	Dec	Jan	Feb	Mar
10/12/11	Meeting with HRSA Central Office and Regional Office Program Integrity Staff and HRSA Division of Financial Integrity	X					
10/19/11	340B Program Review (through internet resources of guidelines and program information) conducted	X					
11/03/11 to 11/11/11	Online training (online tools and Q&A)		X				
11/14/11 to 11/30/11	Select initial set of Covered Entities(CE) for audit/prepare historical files		X				
11/14/11 to 11/30/11	Prepare Audit Plan using 340B guidelines and HRSA Audit Protocol*		X				
12/1/11 to 12/15/11	Prepare Communication Plan; communicate and schedule audit with CE; and send audit plan			X			
1/9/12	Pre-audit interview and Q&As				X		
2/6/12	Begin Audit of Covered Entities**					X	

*HRSA will continue to revise and improve audit guidelines based on results

**Audit of Each Covered Entity is expected to take additional 2 to 3 months for the audit and publication of reports