

**Diana Espinosa
Deputy Administrator,
Health Resources and Services Administration
House Energy and Commerce Committee
340B Hearing Questions for the Record
March 24, 2015**

The Honorable Joseph R. Pitts

- 1. The President's FY2016 Budget Request proposes a new user fee totaling \$7.5 million as a long term financing strategy to support the program's activities. The Budget envisions allowing HRSA to "collect a fee of 0.1 percent of each purchase of 340B drugs from entities participating in the Drug Pricing Programbased on sales data that shall be submitted by drug manufacturers." The goal of this proposal seems like it is to strengthen HRSA's capabilities and grow its capacity to oversee the program – a proposal I think many of my colleagues would support. How would such a fee financially impact an average covered entity? Can you provide detailed legislative specs for this proposal?**

Response: 340B-covered entities receive a significant benefit from participating in the 340B Program, and the proposed user fee allows HRSA to meet the demands of program oversight, the changing marketplace, and ensure the cost of administering the 340B Program is paid for as a small fraction of the received benefit. Without the user fee, the funding necessary to administer the program comes exclusively from appropriations.

The user fee would be 0.1 percent – one cent for every thousand dollars – of the total 340B drug purchases paid by participating covered entities. The vast majority of entities would be assessed a fee less than \$1,000.

The FY 2016 Budget includes appropriations language to authorize the Secretary to collect and spend user fees for the 340B Program, which states:

"Provided, That the Secretary may collect a fee of 0.1 percent of each purchase of 340B drugs from entities participating in the Drug Pricing Program pursuant to section 340B of the PHS Act to pay for the operating costs of such program: Provided further, That fees pursuant to the 340B Drug Pricing Program shall be collected by the Secretary based on sales data that shall be submitted by drug manufacturers and shall be credited to this account, to remain available until expended."

- 2. In the 2007 Patient Definition Notice, HRSA outlined few specific requirements for an entity to qualify its provider-based departments for 340B pricing eligibility. Among them is the requirement that "loose affiliations" would be insufficient because it wouldn't support an appropriate level of clinical nexus between the covered entity and the patient's health care. Has HRSA considered other arrangements beyond "loose affiliations" that should be proscribed under its rules? Is HRSA concerned that the**

340B program is motivating these arrangements, which have consequences (e.g., site of care shift) on programs outside of 340B?

Response: HRSA plans to issue proposed omnibus guidance for public comment later this year. HRSA is unable to provide specific details of the proposed omnibus guidance until it is issued.

- 3. The DSH metric is calculated based on inpatient hospital stays by Medicaid and low-income Medicare beneficiaries. However, hospitals are continuing to see a downward trend in the number of inpatient admissions and are seeing more patients in the outpatient setting.¹ Do you think it makes sense for 340B eligibility to be based on an inpatient metric, when more and more hospital care is being received in the outpatient setting and the program is only applicable to outpatient drugs?**

Response: As you indicate, eligibility for the 340B Program for many hospitals is based in part on the DSH patient percentage calculation, and is statutory. We can provide technical assistance to any proposal you share with us relative to changes in the program authority.

- 4. It is my understanding that entities eligible for the program based on their grantee status may be required to use 340B revenue in accordance with their grant requirements but that eligible hospitals have no such requirement. Is that accurate? For each type of covered entity, please describe what requirements, if any, exist regarding their use of 340B revenue and the source of those requirements?**

Response: The 340B statute does not have requirements for covered entities regarding how revenue must be used. However, HRSA grantees that participate in the 340B Program (*i.e.*, community health centers, Ryan White HIV/AIDS Program grantees and hemophilia treatment centers), do have grant requirements whereby any program income generated must be used consistently with the purposes and conditions of the grantee's federal award. In the case of community health centers, Ryan White HIV/AIDS Programs, and the Hemophilia Treatment Center Program, that would include furthering the project's objectives by serving more patients and providing more comprehensive services.

- 5. Both GAO and OIG testimony alluded to the fact that participating 340B hospitals are not required to disclose how they reinvest any revenue generated from participation in the program—whether they lower costs for the un insured, whether they provide additional charity care, or whether they offer any number of health programs to their**

¹ <http://www.modernhealthcare.com/article/20150127/NEWS/301279903/hospitals-saw-fewer-admissions-in-outpatients-in-2013>

community. Since the purpose of the 340B program is to stretch federal dollars further, it would seem to make sense to require covered entities to report on how they use the revenue from the program. Could HRSA require covered entities to report this information as a condition of program participation and wouldn't this be positive for the program? Why has the agency not done so?

Response: The 340B statute speaks only to covered entity eligibility and compliance requirements and does not specify how 340B savings must be used; therefore, HRSA does not collect this information.

- 6. Avalere data shows that more than two-thirds of 340B hospitals provided less charity care (calculated as a percent of patient costs) than the average of all hospitals - including for-profit hospitals.² Additionally, about a quarter of 340B hospitals provide charity care that represents less than 1% of their costs.³ Do you think these results show that the current hospital eligibility metrics are consistent with the program's original intent? Do you think it is fair that some hospitals that provide minimal charity care should be able to access 340B discounts with no obligation that they pass any of that savings on to patients or invest the savings in care for the uninsured and vulnerable?**

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating covered entities. The 340B Program statute requires drug manufacturers to provide covered outpatient drugs to eligible covered entities at significantly reduced prices. The 340B statute does not specify how the covered entities must use the savings or require that entities pass savings onto their patients (whether they are insured or uninsured).

- 7. A quick search of HRSA's Office of Pharmacy Affairs 340B database showed that the Cedars Sinai Plastic Reconstructive Center in Los Angeles, California is a 340B covered entity. According to a list based on CMS cost report data and analyzed by the American Hospital Directory, Cedars-Sinai is the third-highest grossing non-profit hospital in the U.S. Does it seem incompatible with the program's original intent that a plastic surgery center located in Hollywood is eligible for 340B discounted drugs?**

Response: Based on the information submitted by the covered entity, HRSA has determined that the above-mentioned site is not eligible. The site has been terminated from the 340B Program.

² <http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf>

³ <http://340breform.org/userfiles/Final%20AIR%20340B%20Charity%20Care%20Paper.pdf>

8. In 1996, HRSA issued guidance permitting 340B entities to operate a single contract pharmacy if they did not have an on-site pharmacy. In that guidance, HRSA stated that 340B entities use differing approaches to charging patients for 340B drugs, with some passing through all the savings and others setting a slightly higher price. The 1996 guidance⁴ went on to state, "The Department intends to examine the section 340B pricing activities of covered entities to determine the various approaches used and the rationale for these approaches. However, until it completes its examination of the issue, the Department notes that a modest section 340B markup... does not appear inconsistent with the drug pricing program," so long as savings are used for the purposes of the federal program providing an entity 340B eligibility.

- a. What were the specific findings of the Department's examination of the approaches used by 340B entities in setting prices for 340B drugs dispensed to patients?**
- b. When has the examination completed and released? Since the 1996 guidance was in part premised on the examination, what actions were taken based upon the findings?**
- c. What information does HRSA collect or otherwise have about the markups charged to patients for 340B drugs?**
- d. Are the markups today the "modest" amount envisioned in the 1996 guidance? And how did HRSA take the examination's results into account when it issued the 2010 guidance that expanded the contract pharmacy program?**

Response: A formal examination was not conducted. The Program does not prohibit a covered entity from billing the patient's insurer at a negotiated rate that is higher than the 340B price paid to obtain the drug. The 340B statute is silent on how entities use savings, so HRSA has not collected this information from covered entities. HRSA does not collect information about potential markups charged to patients.

9. Does HRSA believe it would be useful to have authority to share 340B ceiling prices with state Medicaid agencies and, if such authority is provided, how long would it take HRSA to begin sharing such information with the states?

⁴ 61 Fed Reg. 43549, 43551, Aug. 23, 1996.

Response: A 2011 HHS Office of the Inspector General (OIG) Report recommended that HRSA share 340B ceiling prices with states. Section 340B(d)(1)(B)(iii) of the Public Health Service Act specifically limits the disclosure of 340B ceiling prices to 340B covered entities; therefore, HRSA lacks statutory authority to provide the prices to the states.

- 10. We understand that even with the Medicaid Exclusion File, duplicate discounts continue to be an issue for the 340B program. Can you comment on the viability of private sector solutions to eliminate duplicate discounts and promote compliance with federal requirements? Are you aware of any existing private sector programs that help eliminate duplicate discounts (that is, preventing 340B drugs from also collecting a Medicaid rebate)?**

Response: HRSA is aware of at least one product that has been created in the marketplace. However, despite these private-sector products that aim to eliminate duplicate discounts, covered entities are still responsible for evaluating and overseeing compliance with the 340B statutory prohibition against duplicate discounts. Covered entities that, through audits, are found to be in violation of the duplicate-discount prohibition, are subject to repayment for noncompliance.

- 11. Has HRSA conducted any analysis on the financial impact the 340B program has on manufacturers or state Medicaid programs? If so, what have you found?**

Response: HRSA has not conducted this type of analysis.

- 12. Since the contract pharmacy program guidance was issued in 2010, OIG and GAO issued reports indicating that contract pharmacy arrangements create heightened risks for drug diversion. HRSA's expectation in its guidance is that 340B entities would use annual audits performed by independent, outside auditors. However, OIG's February 2014 report found that 23 of 30 340B entities it interviewed had not engaged an independent auditor. Certainly, the violation of HRSA's expectations must concern you, and I know you would welcome statutory clarity on contract pharmacies.**

- a. What action did HRSA take prior to the OIG report to address the lack of independent audits called for in your own guidance?**

Response: The responsibility for contract pharmacy compliance in the 340B Program rests with the covered entity – including oversight of their contract pharmacy arrangements. In 2010, HRSA issued final guidelines requiring that covered entities that choose to use contract pharmacies have mechanisms in place to prevent diversion and duplicate discounts in alignment with the statute. HRSA also requires that covered entities oversee compliance with their contract pharmacy arrangements. HRSA views independent audits as an important compliance tool but

it is only one approach that covered entities can utilize in their oversight of contract pharmacies. Other examples of compliance include the expectation that they “carve out” Medicaid in order to avoid duplicate discounts and the requirement that the covered entity and pharmacy maintain auditable records and policies and procedures to demonstrate compliance with all Program requirements. If HRSA determines that a covered entity is not providing oversight of the contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

b. What action have you taken since the OIG report to see to it that independent audits are conducted? How many 340B entities in each eligibility category are now conducting independent audits?

Response: HRSA continues to audit 340B covered entities and their contract pharmacy arrangements to ensure they are conducting oversight of the contract pharmacy arrangements. HRSA does not collect information as to how many covered entities conduct independent audits of their contract pharmacy arrangements. However, HRSA does ensure that if a covered entity is found not to be providing any oversight of its contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

13. Which types of covered entities are most likely to have large networks of contract pharmacies and what share of entities with large contract pharmacy networks are grantees versus hospitals?

Response: The vast majority of covered entities do not contract with pharmacies. Currently, 27 percent of covered entities utilize contract pharmacy arrangements. Health centers represent the largest proportion of covered-entity sites (48 percent) that have arrangements with contract pharmacies. These arrangements enable health centers to expand the type and volume of care they provide to vulnerable patient populations. For those covered entities that offer reduced price medications to their low-income uninsured patients, contract pharmacies make medications more accessible by offering additional locations and extended hours.

14. HRSA stated in the 2010 Guidance on contract pharmacy that 340B entities are responsible for ensuring compliance of their contract pharmacy arrangements with all 340B Program requirements to prevent diversion and duplicate discounts. HRSA also states that 340B entities must maintain auditable records and are expected to conduct

annual audits of contract pharmacies that are performed by an independent auditor.⁵ Yet the 2104 OIG report that found that 23 of 30 surveyed entities (76.7%) reported they did not use independent auditors for their contract pharmacy arrangements. Given the exponential growth of contract pharmacy arrangements over the years, how can HRSA be sure that contract pharmacies are taking appropriate steps to ensure compliance with the law?

Response: The responsibility for contract pharmacy compliance in the 340B Program rests with the covered entity – including oversight of their contract pharmacy arrangement. If a covered entity is found not to be providing any oversight of its contract pharmacy arrangement, the contract pharmacy is terminated from the 340B Program.

In 2010, HRSA issued final guidelines requiring that covered entities that choose to use contract pharmacies have mechanisms in place to prevent diversion and duplicate discounts in alignment with the statute. HRSA also requires covered entities to oversee compliance with their contract pharmacy arrangements. HRSA views independent audits as an important compliance tool but it is only one approach that covered entities can utilize in their oversight of contract pharmacies. The following program integrity measures are in place for HRSA to provide oversight of covered entities that utilize contract pharmacies:

- Through its audits of covered entities, HRSA samples 340B drugs at the contract pharmacy and reviews contract pharmacy compliance.
- Covered entities must attest to compliance at the contract pharmacy during the annual recertification process.
- HRSA’s Bureau of Primary Health Care, which oversees the health center program representing the largest proportion of covered entities using contract pharmacies, has integrated program integrity questions into their regular site visits, including questions regarding contract pharmacies.
- HRSA has also developed educational tools and resources in order to inform all 340B stakeholders and improve overall program integrity. Some examples of the resources and tools include:
 - Webinars: Monthly HRSA webinars for all stakeholders to address patient eligibility, compliance with Medicaid requirements, prevention of duplicate discount, and how to prepare for an audit. In addition, high performing 340B covered entities are identified and share best practices with other participating sites via webinars and other forums.
 - Sample policies and procedures that can be adapted to a particular site.
 - Specific guidelines on the determination of patient eligibility for those individuals receiving 340B drugs.

⁵ <http://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

- Call Center and 340B University (through the 340B Prime Vendor Program): Through 340B University courses, HRSA is able to address eligibility/database issues, diversion and patient eligibility, and prevention of duplicate discounts. A call center is also available to all stakeholders to answer questions regarding implementation of the 340B Program.

Manufacturers can also audit contract pharmacies through the participating covered entity once the audit is approved by HRSA.

- 15. HRSA’s 2010 guidance⁶ allowing an unlimited number of contract pharmacies was justified on the basis that “some patients currently face transportation barriers or other obstacles that limit their ability to fill prescriptions. It would be a significant benefit to patients to allow the use of more easily accessible, multiple contract pharmacy arrangements” which would “create wider patient access by having more inclusive arrangements in their communities.” Yet the guidance did not include any standards that would assure that contract pharmacy arrangements would benefit patients in this way, or any data collection that would allow us to determine whether patients are getting better access in their communities. Most troubling, in 2014 the Office of the Inspector General issued a report⁷ showing that of 15 DSH hospitals interviewed, more than half reported not offering the 340B-discounted price to uninsured patients in even one of their contract pharmacy arrangements, meaning they pay the full, non-340B price. Please explain how the contract pharmacy program HRSA created in the 2010 guidance meets HRSA's stated goal of creating wider access for patients in their communities when patients do not get a discount.**

Response: The 340B statute is silent as to the drug-delivery systems covered entities may utilize. The 340B contract pharmacy guidelines did not create a new right to use contract pharmacy arrangements, but recognized that covered entities already contracted for pharmacy services. HRSA’s contract-pharmacy guidelines are aimed at making certain that if entities are going to contract with these pharmacies, the arrangements are constructed in ways that comply with 340B requirements against diversion and duplicate discounts. For example, for HRSA grantees that participate in the 340B Program (*i.e.*, health centers, Ryan White HIV/AIDS Program grantees and hemophilia treatment centers among others), there are grant requirements whereby any program revenue generated must be used consistently with the purposes and conditions of the grantee’s Federal award. In the case of health centers, Ryan White HIV/AIDS Programs and the Hemophilia Treatment Center Program, that would include furthering the project’s objectives by serving more patients and providing more comprehensive services.

⁶ 75 Fed Reg. 1072, 1073, March 5, 2010.

⁷ OIG Memorandum Report: “Contract Pharmacy Arrangements in the 340B Program,” Feb. 4, 2014, pg.14

Covered entities without an in-house pharmacy would be unable to participate in the program without the ability to contract with pharmacies. However, in the 340B Program, contract pharmacy arrangements are not common. Currently, only 27 percent of covered entities use contract pharmacy arrangements. Covered entities report that common examples of use of the savings generated include clinical pharmacy programs for medication adherence or medication management, and sliding fee discounts for other services. In addition, covered entities that use contract pharmacies benefit from the reduced costs incurred by not having to undertake the space, staffing, and capital costs that would be required to run an in-house pharmacy.

16. What specific indicators of success or failure has HRSA publicly identified for the contract pharmacy program? How does HRSA track and publicly report on whether the program's results are achieving the specific goals HRSA stated in its own guidance, and how does HRSA respond when the program is not working as HRSA envisioned?

Response: HRSA places the highest priority on the program integrity of the 340B Program, and will continue to explore all avenues for improving the oversight of the Program. HRSA's role is to ensure covered entities and manufacturers are in compliance with 340B Program requirements, and our program integrity efforts focus on specific compliance elements. The covered entity compliance requirements for contract pharmacies require the covered entity to have mechanisms in place to prevent diversion and duplicate discounts. Per the 340B statute and HRSA's 2010 guidelines, all covered entities are required to maintain auditable records and provide oversight of their contract pharmacy arrangements.

As a result of our enhanced focus on compliance issues, there has been more attention paid to compliance of program requirements by covered entities, which has resulted in increased self-disclosures and voluntary terminations of contract pharmacies initiated by the covered entities when requirements were not being met. Through its audits of covered entities, HRSA also reviews samples of 340B drugs at the contract pharmacy and reviews contract pharmacy compliance. Through FY 2014, HRSA has completed 244 audits of covered entities.

17. Given the concerns that have been raised about the integrity and accountability with some parts of the program, I'm interested in better understanding your audit notice and hearing process. Can you elaborate a bit on that, as well as what you can-and cannot-use to terminate a covered entity or manufacturer from the program? For example, I believe the statute only envisions repayment if there is a proven case of a duplicate discount or diversion?

Response: HRSA employs a systematic approach to program integrity that begins with initial certification upon entry into the program and continues with annual recertification for all entities to ensure compliance with program requirements. We conduct on-site audits using a risk-based selection method, and in instances where there are potential compliance

issues, HRSA conducts targeted audits. A covered entity receives a Final Report, and is granted, per statute, the opportunity for “notice and hearing,” by which they can submit one written disagreement to HRSA with supporting documentation. If a covered entity submits a disagreement, HRSA considers their additional points, which may result in adjusted findings. In instances of an adjusted finding, HRSA then issues a revised Final Report. Once an audit report is finalized, the findings and any associated corrective action will be summarized on the HRSA public website. If findings are included in the Final Report, the covered entity is required to submit a Corrective Action Plan to HRSA as well as a Public Letter informing manufacturers of the potential need for repayment.

Since 2012, HRSA has terminated over 870 covered entities for failure to recertify. HRSA terminates covered entities from the 340B Program when we find they are no longer eligible for the program. The reasons for termination include:

- a covered entity’s Disproportionate Share Hospital (DSH) percentage falls below the DSH adjustment percentage threshold;
- the covered entity loses their qualifying grant or designation;
- a hospital violates the Group Purchasing Organization prohibition;
- a covered entity fails to annually recertify; or
- if after a HRSA audit and after notice and hearing, a covered entity is found to have violated diversion or duplicate discount prohibitions, HRSA can terminate the covered entity if they fail to provide HRSA a Corrective Action Plan.

Section 340B(d)(2)(B)(v) of the Public Health Service Act authorizes the Secretary of HHS to impose sanctions on covered entities, who knowingly and intentionally violate the diversion prohibition. The statute allows removal from the Program if the diversion violation is systematic and egregious. We plan to address covered entity sanctions in future guidance.

With regards to manufacturers, in any instance of an overcharge, manufacturers are required to issue the covered entity a refund. The manufacturer may be subject to termination from the 340B Program for violations of statutory requirements.

18. What sanctions does HRSA impose or plan to impose for violations of statutory requirements or HRSA guidance discovered in audits, and what appeal process is open to covered entities? How, if at all, does the lack of regulatory authority affect HRSA’s ability to impose sanctions on covered entities or manufacturers?

Response: As discussed in an earlier question, after audit, notice and hearing, if a covered entity is found in violation of diversion or duplicate discounts, a covered entity must repay manufacturers. The notice and hearing process allows covered entities to submit one written disagreement to HRSA with supporting documentation after they receive HRSA’s Final audit report. If a covered entity submits a disagreement, HRSA considers their additional points, which may result in adjusted findings. HRSA then issues a revised Final

Report. Once an audit report is finalized by HRSA, the findings and any associated corrective action will be summarized on the HRSA public website. If findings were included in the Final Report, the entity is required to submit a Corrective Action Plan as well as a Public Letter informing manufacturers of the potential need for repayment.

In addition to repayment for violations of diversion and duplicate discounts, section 340B(d)(2)(B)(v) of the Public Health Service Act authorizes the Secretary of HHS to impose additional sanctions on covered entities who knowingly and intentionally violate the diversion prohibition. The statute allows removal from the Program if the diversion violation is systematic and egregious. We plan to address covered entity sanctions in future guidance. With regards to manufacturers, in any instance of an overcharge, manufacturers are required to issue the covered entity a refund.

19. MedPAC’s recent public meeting raised the possibility of extending the 340B discount to seniors participating in Medicare. The idea is that the Medicare’s drug reimbursement is ASP+6, while the 340B program, yields savings of 20 to 50 percent off of commercial prices. If Congress were to modify the 340B statute, seniors—and the Medicare Trust Fund—could potentially save money. What considerations – cautions or encouragements – would you offer on this policy proposal?

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities. While the statute does require manufacturers to provide covered outpatient drugs to eligible covered entities, it is silent on how the covered entity is to use those savings. We would be happy to work with the Congress to provide technical assistance on any specific proposals regarding the 340B Drug Pricing Program that are submitted for our review.

20. At the hearing, you indicated that despite growth in the number of covered entities, 340B sales have remained at about 2 percent of overall pharmaceutical sales. Please describe how HRSA calculated this figure, including the data sources used.

Response: HRSA is able to track the majority of 340B pharmaceutical purchases through its 340B Prime Vendor and the pharmacy wholesaler relationships. The IMS Institute for Healthcare Informatics reports annually the total U.S. spending on pharmaceuticals. The total percentage of 340B spending in the market is determined using the following formula:

$$\frac{340B \text{ Spending on Pharmaceuticals}}{\text{Total U.S. Spending on Pharmaceuticals}} = 340B \text{ Percentage of Pharmaceutical Sales}$$

For example, in 2013, 340B purchases totaled \$7,123,638,209 and IMS reported U.S. spending on pharmaceuticals to be \$329,000,000,000. Using the formula stated above:

$$\frac{\$7,123,638,209}{\$329,000,000,000} = 2.17\% \text{ or } 2\% \text{ (rounded)}$$

21. Given that hospitals are making greater use of contract pharmacies compared with other covered entities, do you think the program is working as intended and is meeting its original goal?

Response: Health centers, rather than hospitals, represent the largest proportion of covered-entity sites (48 percent) that have arrangements with contract pharmacies. These health centers benefit from contract pharmacies because those arrangements enable them to expand the type and volume of care they provide to vulnerable patient populations. For those covered entities that offer reduced price medications to their low-income uninsured patients, contract pharmacies make medications more accessible by offering additional locations and extended hours.

While HRSA lacks statutory authority to govern how covered entities use savings, many covered entities have reported to GAO [and others] using the savings generated by contract pharmacies to support numerous activities that enhance access for underserved populations. For example, HRSA grantees that participate in the 340B Program have grant requirements whereby any program revenue generated must be used consistently with the purposes and conditions of the grantee's Federal award. In the case of health centers, Ryan White HIV/AIDS Programs and the Hemophilia Treatment Center Program, that would include furthering the project's objectives by serving more patients and providing more comprehensive services. Other common examples include clinical pharmacy programs for medication adherence or medication management, and sliding fee discounts for other services. In addition, covered entities that use contract pharmacies benefit from reduced costs by not having to incur the substantial space, staffing, and capital costs that would be required to run an in-house pharmacy.

22. What, if any, changes does HRSA think need to be made to the contract pharmacy program?

Response: HRSA plans to issue proposed omnibus guidance for notice and public comment. We are unable to provide specific details of the proposed omnibus guidance until it is issued.

23. Some have argued that the 340B program creates incentives for hospitals to acquire physician practices, especially those with high rates of use of specialty pharmaceuticals, in order to take advantage of the discount drug prices and high drug margin. At the same time, national trends in health care provider consolidations have raised concerns about increased costs to patients and the entire health care system. Is HRSA concerned that the incentives created by the 340B program could be having negative effects on patient's access to affordable health care?

Response: Covered entities in the 340B Program represent a wide range of health care providers, from large hospitals to small rural providers. HRSA recognizes that business decisions are made every day by covered entities, which may or may not pertain to access to 340B prices. We are uncertain what, if any, of the growth in hospital acquisition of physician practices is driven by hospital access to 340B pricing.

Beyond ensuring that the facility meets the definition of a covered entity in statute, HRSA does not have statutory authority to get involved in covered entities' decisions around acquisitions. These entities have varying mechanisms available to ensure compliance with the 340B Program requirements, which may include, but are not limited to, IT infrastructure and staffing. These entities make business decisions accordingly, and HRSA holds them accountable for ensuring compliance with essential 340B program requirements.

24. HRSA posted a letter in early February 2014 regarding the ability of 340B AIDS Drug Assistance Programs (ADAPs) to seek 340B rebates from manufacturers where the ADA P does not purchase the 340B drug outright but rather purchases private insurance for the ADAP enrollee or otherwise pays the enrollee's insurance premium, deductible, or co-insurance or co-payment amount for the drug. The letter suggests manufacturers are not required to pay 340B rebates to ADA Ps in such circumstances.

- a. Can you please confirm whether, as the letter suggests, that manufacturers currently are not obligated to pay such rebates, particularly where the ADAP's expenditures (in whatever form) do not exceed the 340B ceiling price?**

Response: HRSA's February 2014 letter indicated that this issue will be addressed in future policymaking and encouraged manufacturers to continue their current ADAP rebate operations in order to maintain stability in the ADAP program.

- b. If HRSA believes such rebates are or may be required, what processes has HRSA put in place to ensure any drugs subject to such 340B rebates are not also subject to a Medicaid rebate, in violation of the duplicate discount prohibition?**

Response: As required by statute, HRSA established a mechanism which is known as the HRSA Medicaid Exclusion File, to assist covered entities in preventing duplicate discounts. Covered entities are required to inform HRSA at the time they enroll in the 340B Program whether they plan to bill Medicaid for covered outpatient drugs dispensed to Medicaid beneficiaries. If an eligible entity plans to use 340B drugs in billing Medicaid, it must notify HRSA to prevent a duplicate discount, and HRSA lists them on the Medicaid Exclusion File. This file is used by states and manufacturers so they know which drugs cannot have a subsequent rebate under Medicaid.

- c. **When does HRSA expect to issue a rule (or other guidance) on this topic, as referenced in the letter?**

Response: HRSA plans to address the issue in the proposed omnibus guidance for notice and public comment.

25. As you know, the 340B statute prohibits duplicate discounts, which are defined to occur when a drug sold at the 340B price is also the subject of a Medicaid rebate claim by a State Medicaid Program. Since the 340B Program was enacted, Congress also has enacted a mandatory coverage gap discount for Part D drugs. Where a 340B drug is dispensed to a Part D beneficiary, therefore, it is possible that it could be the subject to a 340B discount and a Part D coverage gap discount.

- a. **Does HRSA have any mechanisms in place to ensure manufacturers are not subject to duplicate discounts under the Part D coverage gap program?**

Response: The 340B statute only addresses duplicate discounts as they pertain to the Medicaid program. Therefore, 340B violations of the duplicate discount prohibition are not triggered by other federal insurance programs.

- b. **If not, what does HRSA need in order to implement such a prohibition?**

Response: HRSA is unable to comment without seeing a specific proposal related to this issue.

- c. **To the extent HRSA believes ADAPs are entitled to 340B rebates as discussed above, and HRSA has no controls in place to prevent Medicaid duplicate discounts, isn't it possible that the status quo could expose manufacturers to "triple-dipping" due to 340B, Medicaid, and Part D mandatory discounting?**

Response: HRSA has a mechanism in place to prevent duplicate discounts – the Medicaid Exclusion file. That mechanism is specific to 340B and Medicaid and does not include other Federal programs, as the 340B statute is specific to Medicaid only.

26. When PPACA expanded manufacturer Medicaid rebate liability to managed care utilization, the legislation also expanded the 340B duplicate discount prohibition to apply to managed care utilization. We are now 5 years post-enactment.

- a. **What has HRSA done to implement the duplicate discount prohibition as it relates to Medicaid managed care utilization? If no actions have been taken, please explain why.**

Response: In December 2014, HRSA clarified that the current mechanism in place to prevent duplicate discounts, the Medicaid Exclusion File, was specific to Medicaid Fee-For-Service. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with CMS to develop policy in this regard. HRSA plans to issue proposed omnibus guidance for notice and comment. In the meantime, we are aware that some covered entities have already worked with managed care organizations (MCOs) and state partners to develop models for the prevention of duplicate discounts. HRSA encourages 340B covered entities to work with their states to develop strategies to prevent duplicate discounts on drugs reimbursed through MCOs.

The Honorable Tim Murphy

- 1. Could you provide more detail on the upcoming guidance you mention in your testimony and how it impacts patient definition, eligible prescription, and future hospital eligibility?**

Response: HRSA is unable to speak to the specifics of the proposed omnibus guidance until it has been issued. We expect to issue the proposed omnibus guidance for notice and public comment later this year.

- 2. Could you clarify how you view HRSA's authority to issue and enforce guidance versus rulemaking, in light of statutory limitations and recent court findings?**

Response: In 2014, HRSA planned to issue a proposed omnibus regulation for the 340B Program to establish additional clear, enforceable policy to advance our oversight of covered entities and manufacturers. In May 2014, while the omnibus proposed regulation was in development, the U.S. District Court for the District of Columbia issued a ruling addressing an earlier 340B regulation concerning orphan drugs (certain drugs used to treat rare conditions or diseases). The court invalidated the orphan drug regulation, finding that HRSA lacked explicit statutory authority to issue it. In light of this ruling, HRSA will issue proposed rules where the statute is specific about rulemaking and provide guidance to address critical policy matters raised by 340B Program stakeholders for which there is a lack of explicit regulatory authority. The guidance will enable covered entities and manufacturers to comply fully with statutory 340B Program requirements and will increase the Department's ability to ensure effective implementation, oversight, and monitoring of the 340B Program. HRSA will use the full extent of agency authorities in its efforts to ensure the integrity of the 340B Program.

- 3. Is HRSA aware of any hospitals or hospital systems acquiring a 340B eligible clinic for the purpose of purchasing their outpatient drugs at the 340B discounted price through these clinics?**

Response: HRSA does not have information related to internal business decision-making practices of hospitals, including the decisions that involve acquisitions of other sites. Covered entities in the 340B Program represent a wide range of health care providers, from large hospitals to small rural providers. HRSA recognizes that business decisions are made every day by covered entities, which may or may not pertain to access to 340B prices.

- a. Would you consider the use of the program in this manner to be consistent with the original intent of the program?**

Response: The 340B Program is intended to substantially reduce the cost of covered outpatient drugs to 340B-participating eligible entities in order to stretch scarce Federal

resources. Per statutory authority, HRSA focuses on ensuring covered entities and manufacturers comply with program requirements. If, through the verification process, an entity meets all of the eligibility requirements, the entity is listed on our database and may begin purchasing drugs on the first day of the calendar quarter.

b. Would the use of the 340B program in this manner be identified in the audits conducted by HRSA?

Response: HRSA's audits of 340B covered entities are focused on areas of program compliance with the 340B statute and guidelines, including covered entity eligibility, diversion and duplicate discounts. Beyond ensuring that the facility meets these compliance standards, HRSA's audits do not examine covered-entity independent business strategies or decisions.

The Honorable Leonard Lance

- 1. It has come to my attention that some 340B hospitals, often with the assistance of consultants, have been retrospectively "reclassifying" past, noncompliant 340B purchases as 340B compliant purchases. These "reclassified" purchases are then "banked" in an attempt to justify additional 340B purchases-and this is done without informing OPA or the manufacturer. 340B program guidance states that HRSA does not, and has not in the past, endorsed any type of retrospective "correction" or "reclassification" process by a covered entity. Nevertheless, my understanding is that the practice is continuing. What steps is the Agency taking to address this issue?**

Response: HRSA has not authorized the use of a credit/rebill, banking, or similar process to re-characterize previous transactions. Covered entities participating in the 340B Program are responsible for requesting 340B pricing at the time of the original purchase. If a covered entity wishes to reclassify a previous purchase as a 340B purchase, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. The covered entity retains responsibility for ensuring full compliance and integrity of their use of the 340B Program.

- 2. Some 340B stakeholders are concerned about evidence suggesting that some hospitals have changed the admission status of their patients for purposes of increasing the amount of 340B discounts the hospital receives. There have been expressions of concern, for instance, that some hospitals have delayed or otherwise manipulated patients' inpatient admissions in order to secure the 340B spread on a drug as an "outpatient" drug.**

- a. Are you aware of this practice?**

Response: Covered entities are required to have in place a consistent process for defining inpatient and outpatient for purposes of the 340B Program. HRSA audits this information while on site to ensure 340B drugs are not provided to inpatients. If drugs are provided to inpatients, HRSA considers this a finding and the covered entity must repay the manufacturer.

- b. What is the government doing to monitor and identify instances where patients' care pathways are being altered in an effort to capture 340B discounts?**

Response: HRSA audits entities' compliance with 340B program requirements, including current 340B patient guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)). If HRSA finds a covered entity is not following patient-definition guidelines and has diverted 340B drugs, the covered entity is required to repay the manufacturer.