

ONE HUNDRED FOURTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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April 20, 2015

Ms. Diana Espinosa, MPP
Deputy Administrator
Health Resources and Services Administration
5600 Fishers Lane
Parklawn Building, Room 14-71
Rockville, MD 20857

Dear Ms. Espinosa:

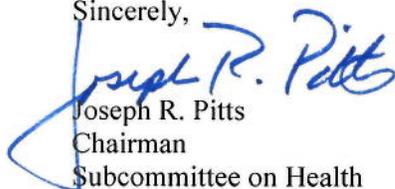
Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Monday, May 4, 2015. Your responses should be mailed to Adrianna Simonelli, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to Adrianna.Simonelli@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,


Joseph R. Pitts
Chairman
Subcommittee on Health

cc: The Honorable Gene Green Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

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 Program....based 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?
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?
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?
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?
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 uninsured, whether they provide additional charity care, or whether they offer any number of health programs to their 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?
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

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

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

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

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?

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 US. Does it seem incompatible with the program's original intent that a plastic surgery center located in Hollywood is eligible for 340B discounted drugs?
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 was 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?
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?
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)?
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?

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

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?
 - 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?
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?
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?
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 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.
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?

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

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

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?
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 manufactures?
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?
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.
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?
22. What, if any, changes does HRSA think need to be made to the contract pharmacy program?
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?
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 ADAP 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 ADAPs 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?
 - 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?
 - c. When does HRSA expect to issue a rule (or other guidance) on this topic, as referenced in the letter?

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

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?
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?
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?
 - a. Would you consider the use of the program in this manner to be consistent with the original intent of the program?
 - b. Would the use of the 340B program in this manner be identified in the audits conducted by HRSA?

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?

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?
 - 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?