

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. Ann Maxwell
Assistant Inspector General for Evaluations and Inspections
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Ms. Maxwell:

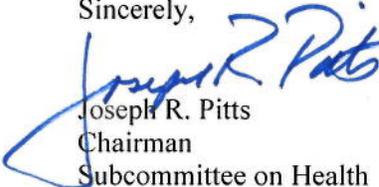
Thank you for appearing before the Subcommittee on Health on Tuesday, March 24, 2015, to testify at the hearing entitled "Examining the 340B Drug Discount Program."

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. HRSA had been preparing a regulation to address the definition of a patient and hospital eligibility, but withdrew its proposal last year following a May 2014 federal district court ruling which found that HRSA's rulemaking authority for the 340B Program is limited to specified areas. HRSA has explained that the agency will be proposing *guidelines* later this year to address those issues. However, as a practical matter, HRSA will be effectively just writing suggestions they have little ability to enforce. Are you aware of any other health care agency in recent history whose hands have been tied in this manner, by not being able to write rules governing the program they administer? In the interest of government accountability and program integrity, is this concerning to you?
2. Your testimony noted more transparency is needed in the 340B program's ceiling prices and Medicaid Claims data for 340B-purchase drugs. What should Congress do to fix HRSA's transparency problems?
3. What are the best practices for CMS, HRSA and the states to prevent duplicate 340B discounts and Medicaid rebates?
4. What is the volume of 340B prescriptions that are going through contract pharmacies?
5. The OIG report found that several contract pharmacy programs do not provide discounts on prescription medicines to uninsured individuals, the increased use of contract pharmacies may be resulting in a greater risk of dispensing 340B drugs where 340B drugs aren't permitted, and the sheer growth of the program heightens the concern that self-policing may be insufficient.
 - a. Given these facts, do you think the agency's 2010 contract pharmacy sub-regulatory guidance should be reassessed or reevaluated to determine its appropriateness? What, if any, suggested changes do you have regarding the contract pharmacy program?
6. In 2010, HRSA issued guidance allowing entities to have an unlimited number of contract pharmacies. Even though the 340B statute does not mention the use of contract pharmacies, it has now become one of the biggest drivers for program growth, and as OIG's 2014 report noted, the use of contract pharmacies creates complications in preventing drug diversion and duplicate discounts. I wondered if the OIG has seen a correlation with increased incidence of duplicate discounts or diversion in contract pharmacies? If so, should certain parameters be in place (e.g., limits on the size or geographic reach of contract pharmacy networks) for contract pharmacies under the 340B programs to ensure program integrity?
7. Do you believe that, with limited dollars and time, scarce resources for oversight should be targeted to the greatest vulnerabilities? If so, what covered entities provide the greatest risk to the integrity and accountability of the program? (Note: while I realize the contract pharmacy vulnerabilities, I'm specifically interested in the type of covered entity.)
8. Given HHS OIG's ongoing work, I wondered if the OIG has reviewed whether the growth in the 340B program has shifted the costs to other parts of the health care system. Has the OIG reviewed whether the 340B program has motivated hospitals to acquire practices and the impact of that behavior on the Medicare program because of reimbursement differences between clinics and hospitals? Has the OIG considered whether the 340B program discourages use of cheaper generic drugs?

9. National trends in health care provider consolidations have raised concerns from health economists about increased costs to Medicare and the entire health care system. I've heard reports that hospitals are buying up community-based cancer clinics which do not at the time of purchase qualify for the 340B program. However, these clinics are later brought under the hospital umbrella. A June 2014 Berkeley Research Group study¹ estimated that these dynamics led to almost \$200 million in additional costs over a three-year period to Medicare beneficiaries who faced greater costs being billed by a hospital. What policy remedies do you envision could reduce costs to seniors?

10. 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?

¹ http://www.thinkbrg.com/media/publication/454_Site_of__Care_Chemotherapy.pdf