GREG WALDEN, OREGON
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

August 2, 2018

Dr. Debra Draper
Director
Health Care
U.S. Government Accountability Office
441 G Street, N.W.
Washington, DC 20548

Dear Dr. Draper:

Thank you for appearing before the Subcommittee on Health on July 11, 2018, to testify at the hearing entitled "Opportunities to Improve the 340B Drug Pricing 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. To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on August 16, 2018. Your responses should be mailed to Dan Butler, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to dan.butler@mail.house.gov.

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

Sincerely,

Michael C. Burgess, M.D.
Chairman
Subcommittee on Health

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

Attachment

Attachment — Additional Questions for the Record

The Honorable Michael C. Burgess, M.D.

1. Current law allows for drugs that have been given the orphan drug designation to be exempted from 340B Program discounts for certain rural facilities, namely Rural Referral Centers, Sole Community Hospitals, Critical Access Hospitals, and Free-Standing Cancer Centers. This exemption has the ability to affect access to needed treatments in these rural areas, as small, rural facilities would not be able to afford these drugs without the 340B discount.

    a. Has the GAO ever considered implications of the orphan drug program on drugs purchased through the 340B program? If so, what have been your findings? If not, would the GAO consider reviewing the orphan drug exclusion for 340B drugs?

The Honorable H. Morgan Griffith

1. In your report you found that HRSA audits do not fully assess compliance with the 340B Program prohibition on duplicate discounts for drugs prescribed to Medicaid beneficiaries. Specifically, manufacturers cannot be required to provide both the 340B discount and a rebate through the Medicaid Drug Rebate Program. However, HRSA only assesses the potential for duplicate discounts in Medicaid fee-for-service and not Medicaid managed care. As a result, it cannot ensure compliance with this requirement. Did GAO find specific evidence of duplicate discounts occurring in instances of Medicaid managed care?

The Honorable Gus M. Bilirakis

1. While the number of audits increased in the first couple of years HRSA did them, can you explain why they have been capped at 200 for the past three years?

2. Does HRSA re-audit a covered entity after a corrective action plan is submitted to ensure compliance and before they close the audit?

3. Of the 72% of covered entities with findings of noncompliance from these audits, how many of those noncompliance issues were duplicate discounts and/or diversion? Is this something that can be addressed through better tracking software?

4. Finally, I also have a question regarding generic vs. brand name drugs. From your research, can you say whether or not the program encourages the use of brand name over generic drugs?

The Honorable Billy Long

1. Your report indicates that disproportionate share hospitals have, on average, 25 contract pharmacies per hospital. And 45 percent of disproportionate share hospitals have at least one contract pharmacy that is more than a thousand miles away from the hospital itself. You found that use of contract pharmacies expands distribution networks and thereby generates revenue to covered entities. Finally, your report notes that due to lack of specific guidance, covered entities often perform minimal contract pharmacy oversight. Would you consider this a program abuse?

2. Would oversight of the 340B program be improved if covered entities were forced to disclose the terms of their arrangements with contract pharmacies and TPAs?

The Honorable Richard Hudson

1. Amazon recently announced it will acquire PillPack, a company that packages, organizes and is licensed to ship prescriptions in 49 states. The company sends consumers packages with the specific number of medications they're supposed to take at specific times. Amazon's market decision could possibly result in lower costs for consumers, though it could add new pressures to other pharmacy retailers who have a bricks-and-mortar business model. Given the challenges with the current lax oversight of contract pharmacies, do you see anything that would prohibit Amazon – or another similarly situated online company – from rapidly expanding in the contract pharmacy business?

2. On page 32 of the report, GAO found that some patients are required to cover the cost of a 340B dispensing fee. Should Congress establish a new policy prohibiting pharmacies and covered entities from charging patients a dispensing fee for 340B drugs?

3. Are you aware of any regulatory authority that HRSA has to audit or collect information about the TPAs, who are also generating revenue as part of the 340B program?

The Honorable Chris Collins

1. 25 of the 55 covered entities you surveyed (45 percent) offered no discounts to low-income, uninsured patients on the price of drugs dispensed at contract pharmacies, including 16 of 28 hospital entities (57 percent). No discount whatsoever to the very populations intended to be helped by the 340B program. The contract pharmacies and the covered entities generate income while charging full price to poor, uninsured patients? And this problem seems to be getting worse, not better: in 2014, OIG issued a report in which 26 percent of covered entities did not discount to the uninsured through their contract pharmacies. Now we're at 45 percent? Do you believe that all covered entities should be required to share the 340B discount with patients?

2. You explain in your report that in addition to flat per-prescription fees, many of the contracts GAO reviewed required that covered entities pay a percentage of the revenue generated by

each prescription to the contract pharmacy. 12 to 20 percent, you found. Is it possible that this incentive causes contract pharmacies to seek out 340B eligible units, perhaps in violation of the prohibition on diversion? Is it possible that this incentive causes contract pharmacies to choose higher cost medicines when lower cost medicines are available?

The Honorable Earl L. "Buddy" Carter

1. Thank you for taking the time to testify before the Subcommittee this morning. Today's hearing marks the third such hearing on the 340B program since July of last year. In the report that GAO released on June 28th, it makes a number of recommendations on areas of improved oversight that HRSA could take to improve the program. In the process of putting this report together, what did GAO find on why HRSA has not adequately enforced the underlying statute?

The Honorable Frank Pallone, Jr.

1. Dr. Draper, there are thousands of contract pharmacy arrangements-Yet, it seems as if the sample size for this report was quite small.
    a. Why was the sample size for this report so small?
    b. Would you say these findings are generalizable to the program as a whole? (no)
    c. Is it fair to say we should use this as simply a random sample, and not apply the findings of this report as a rule to the whole program?
2. Dr. Draper, of the recommendations made by GAO in this report, what are the top two recommendations the Committee should consider most closely?