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ONE HUNDRED FIFTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
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August 2, 2018

Dr. Charles E. Daniels
Pharmacist-In-Chief and Associate Dean
University of California, San Diego
9500 Gilman Drive
La Jolla, CA 92093

Dear Dr. Daniels:

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. One thing that has been consistently reported by the GAO, HHS OIG, as well as published studies in JAMA (Journal of the American Medical Association) and Health Affairs, is the lack of transparency in the 340B program. Increased reporting, of the right measures, would allow Congress to understand how the 340B program dollars are being used to meet the health care needs of vulnerable patients. I find it interesting that some, but not all, 340B hospitals continue to say that on the one hand "they already have extensive reporting" but on the other hand "adding reporting would be onerous". This is circular logic. Hospitals do have the infrastructure to report measures – as they have emphasized that they currently have extensive reporting--- but some seem less interested in working with Congress to make sure that the measures reported on help improve the program. I think that we have lost sight of the fact that this program is completely VOLUNTARY. No one is forcing any entity to participate, and those who do not want to improve transparency can also choose to not participate in the program. Why do you think that some hospitals continue to say they cannot report measures?

The Honorable John Shimkus

1. On page 4 of your written testimony you noted that UCSD does not accept an "all in" clause from contract pharmacies. Can you explain what that means and why UCSD does will not accept that language? Do you think smaller entities have the ability to negotiate this same language? Does Congress need to intervene here?

The Honorable Robert E. Latta

1. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

The Honorable Leonard Lance

1. How do you believe HRSA could more efficiently administer and oversee this program?

2. What actions do you take to ensure compliance with existing regulations and guidelines set forth by HRSA?

The Honorable H. Morgan Griffith

1. Since entering the 340B program, has your hospital acquired "child sites", and if so, what is the reasoning behind these purchases? What types of practices has your hospital-acquired?

The Honorable Gus M. Bilirakis

1. My colleague Dr. Burgess has a discussion draft that would amend the Public Health Service Act to require the Secretary of Health and Human Services to conduct audits under the 340B drug discount program in accordance with generally accepted government auditing standards. I think this is a good idea and one that would help improve the audits HRSA performs moving forward.

    a. Is there evidence that indicates HRSA's audits have increased the integrity of the 340B program?

    b. How do you think HRSA could best assess noncompliance? How could they ensure compliance before closing an audit?

The Honorable Billy Long

1. In instances where a covered entity passes on the 340B discount to the patient in an in-house pharmacy, why would they not provide that same discount at one of their contract pharmacies?

2. In what ways do you all benefit from contract pharmacy arrangements, and how do they help you achieve your mission?

3. Finally, do you think HRSA should issue guidance on how to determine patient eligibility for drug discounts?

The Honorable Larry Bucshon

1. How do you calculate your 340B savings, and do you set aside these savings for specific programs and initiatives, or do they go into a general fund?

2. Are covered entities required to report their savings to HRSA, and if not, does HRSA keep track of 340B savings through some other mechanism?

3. Is HRSA tracking how 340B revenue is spent?

4. Is there evidence that indicates covered entities are using 340B revenue for the original intended purposes of the program?

5. How do you know that your 340B savings are benefitting low income and uninsured patients, and what do you do to ensure that these patients can afford their prescriptions?

6. Would you support legislation to track how 340B savings are spent, and do you have any ideas or recommendations on how that would work?

The Honorable Susan W. Brooks

1. Can you describe the types of comprehensive services that 340B covered entities provide that are not normally seen in non-340B hospitals?

2. In your opinion, what would be the best metric to determine an entity's commitment to serving low-income and uninsured individuals?

The Honorable Richard Hudson

1. Does your entity provide 340B patients with drug discounts? How do you assess a patient's ability to pay for their prescriptions?

2. What percentage of your patients receive free medicine from a patient assistance program that is offered by a biopharmaceutical company or other entity?

The Honorable Earl L. "Buddy" Carter

1. What level of charity care is your hospital providing, and how did you come up with that number?

2. Are child sites required to abide by the same HRSA obligations as the parent site?

The Honorable Frank Pallone, Jr.

1. One of the bills before us—the Protecting Safety-Net 340B Hospitals Act—would raise the DSH percentage for hospital eligibility to such a degree that more than half of all hospitals would be eliminated from the program—including 50 such hospitals in nearly every member of this Committee's districts. The premise for this legislation is presumably that the program is growing at an explosive rate.

    a. Dr. Daniels—do you believe that we can improve access to care for vulnerable patients through 340B without diminishing or cutting the program? Is the 340B program growing at an explosive rate?

2. The 340B program plays a critically important role in our health care system, and the countless hearings had in the Committee on this topic have reaffirmed that point on both sides of the aisle. However it is very important to make certain those dollars do, in fact, go towards expanding services as the statute dictates and that all covered entities are carrying out the 340B program with the people it is intended to serve at the center of any policy decision and in full and transparent compliance with the law.

    a. Dr. Daniels, can you explain the complexity of tracking savings from 340B discounted drugs? How does UCSD ensure these dollars go towards expanding

services for vulnerable patients? Please provide the Committee with any relevant or illustrative documentation to that effect.

3. On June 1, HRSA issued a final rule delaying the implementation of the 340B Drug Pricing Program Ceiling Price and Civil Monetary Penalties regulation until July 1, 2019. In the final rule on the delay, HRSA notes that this delay will "allow a more deliberative process of considering alternative and supplemental regulatory provisions and to allow for sufficient time for any additional rulemaking…HHS intends to engage in additional or alternative rulemaking on these issues, and believes it would be counterproductive to effectuate the final rule prior to issuance of additional or alternative rulemaking on these issues."

    a. Can you describe and provide some information on the impact of this final rule to your institution? How would having access to ceiling prices change how the program is administered?

4. As you know, the Medicare program has recently implemented a nearly 30 percent cut to 340B hospitals.

    a. Please describe the impact this change will have on your ability to care for patients.

5. The recent GAO report confirms that contract pharmacies play an essential role in helping uninsured and low-income patients get needed care, including, but not limited to, prescription drugs. However, GAO notes that HRSA needs to provide additional oversight over the contract pharmacies. While the agency did not agree with all of GAO's recommendations, there were important points made on certain areas for improvement.

    a. Dr. Daniels, can you describe how UCSD uses its contract pharmacy arrangements to increase access for patients? What types of contract pharmacies does UCSD have? What oversight measures are in place in order to maintain compliance with program regulations? How does UCSD make the decision to enter into a contract pharmacy arrangement?