U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

August 10, 2018

The Honorable Michael C. Burgess
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Dear Mr. Chairman

This letter responds to your request that we address questions submitted for the record related to the July 11, 2018, hearing entitled *Opportunities to Improve the 340B Drug Pricing Program*. GAO's responses to these questions are enclosed.

If you have any questions about this response or need additional information, please contact me at draperd@gao.gov or call (202) 512-7114.

Sincerely yours,

Debra A. Draper
Director, Health Care

Enclosure

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?**

    GAO has not analyzed or assessed implications of the orphan drug exclusion on drugs purchased through the 340B program. We would be happy to work with your staff to discuss your concerns related to the orphan drug exclusion and potential future work for GAO.

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?**

    Our study did not include an independent review of duplicate discounts. Rather, our study examined HRSA's efforts to ensure compliance with 340B Program requirements, including the prohibition of duplicate discounts, at contract pharmacies. As noted in our report, HRSA's audits do not include a review of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care. However, during the course of our review, we did see a letter from HRSA's audit of a covered entity that identified the potential for duplicate discounts in Medicaid managed care. HRSA officials told us that they did not take any action to review this potential violation because they had yet to issue guidance related to duplicate discounts in Medicaid managed care.[1] Additionally, as noted in our report, 8 of the 10 covered entities' we spoke with described challenges working with their states and local Medicaid managed care organizations to ensure that duplicate discounts were not occurring and some covered entities acknowledged that they did not

[1]HRSA has reported that effective April 1, 2018, if the agency becomes aware of the potential for such duplicate discounts in Medicaid managed care during the course of an audit, then it will note this in the audit report for the covered entity. If the audit of the covered entity results in findings, then the entity would be required to indicate how it will address the duplicate discounts.

have assurance that duplicate discounts were not occurring with their Medicaid managed care claims.

GAO was asked to assess federal, state, and covered entity efforts to prevent duplicate discounts in both Medicaid fee-for-service and managed care. GAO recently began this review.

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?**

   During our review, we did not obtain information on why HRSA decided to cap the number of audits conducted to 200 per year. We did note in our report that beginning in fiscal year 2017 HRSA contracted with The Bizzell Group to perform the audits on its behalf. HRSA spent $3.8 million in fiscal year 2017 for 340B Program audit services.

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

   HRSA does not re-audit a covered entity after a corrective action plan is submitted to ensure compliance and before they close the audit. In general, HRSA closes the audit when a covered entity submits a letter attesting that its corrective action plan has been implemented and any necessary repayments to manufacturers have been completed. Beginning April 1, 2018, HRSA requires the 10 percent of covered entities that are subject to targeted audits to provide documentation that they implemented their corrective action plans prior to HRSA closing the audits.[2] However, it still relies on the remaining 90 percent of audited covered entities to self-attest to their compliance with program requirements.

   As noted in our report, aside from the self-attestation, HRSA's only mechanism to ensure that the majority of audited covered entities have implemented their corrective action plans is to re-audit the entities. During our review the agency told us that it has re-audited 21 covered entities, and based on those re-audits, determined that 1 entity did not fully implement its corrective action plan from the original audit. However, we found that of the 19 re-audited covered entities for which results were available, 12 had similar findings of noncompliance in their second audits, as were identified in their original audits (e.g., diversion findings in both audits), 3 of which were caused by the same issue, according to information provided to us by HRSA.

   To help improve its oversight we recommended that HRSA require all covered entities to provide evidence that their corrective action plans have been successfully implemented prior to closing audits.

[2]HRSA currently audits 200 covered entities per year; less than 2 percent of covered entities. Approximately 90 percent of the audits conducted each year are of covered entities that are randomly selected based on risk-based criteria, while the remaining 10 percent of audits are of covered entities that are targeted based on information from stakeholders such as drug manufacturers.

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?**

   Of the 813 audits from which results were posted on HRSA's website as of February 8, 2018, 380 had diversion and 206 had duplicate discount findings. However, as noted in our report, HRSA's audits only assess the potential for duplicate discounts in Medicaid fee-for-service. They do not include a review of covered entities' processes to prevent duplicate discounts for drugs dispensed through Medicaid managed care despite the fact that there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than fee-for-service. Thus, the number of findings related to duplicate discounts compliance issues would likely be higher if HRSA audits include an assessment of duplicate discounts in managed care. The use of software was not within the scope of our work.

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?**

   For our report we did not review whether the 340B Program encourages the use of brand name over generic drugs. In a few of the contracts we reviewed between covered entities and contract pharmacies, we did note that the contracts either excluded generic drugs from being purchased at the 340B price or limited the use of the 340B Program to brand drugs.

   While not specific to the use of brand versus generic drugs, we issued a report in June 2015 that compared spending for Medicare Part B drugs, including oncology drugs, at certain hospitals that participated and did not participate in the 340B Program. [3] In that report, we found that, in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at certain 340B hospitals than at non-340B hospitals. This indicated that, on average, beneficiaries at these 340B hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals analyzed. We concluded that because Medicare pays hospitals at set rates for Part B drugs regardless of their costs for acquiring them, there was a financial incentive at hospitals participating in the 340B Program to prescribe more drugs or prescribe more expensive drugs to Medicare beneficiaries. In the report, we recommended that Congress consider eliminating the incentive to prescribe more drugs or more expensive drugs than necessary to treat Medicare Part B beneficiaries at 340B hospitals. Since that time, CMS has promulgated regulations that reduced the rates paid to selected 340B hospitals, including those covered by our analysis, for Medicare Part B drugs for calendar year 2018.[4]

<u>The Honorable Billy Long</u>

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**

[3]See GAO, *MEDICARE PART B DRUGS: Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals*, GAO-15-442, (Washington, D.C.: June 5, 2015)

[4] See, 82 Fed. Reg. 59216 (Dec 14, 2017.)

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?

Use of contract pharmacies in the 340B Program is governed HRSA guidance. The March 2010 HRSA guidance on contract pharmacy services allows covered entities to have an unlimited number of contract pharmacies. The guidance also does not include any limitations on to the location of the pharmacies or the distance between covered entities and their contract pharmacies. The guidance does specify that covered entities are responsible for overseeing their contract pharmacies to ensure that drugs the entity distributes through them comply with 340B Program requirements. However, as noted in your question, we found that HRSA's guidance for covered entities lacks specificity and due, at least in part, to this lack of specific guidance some covered entities performed minimal contract pharmacy oversight. As a result, we recommended that the Administrator of HRSA provide more specific guidance to covered entities regarding contract pharmacy oversight, including the scope and frequency of such oversight. The Department of Health and Human Services concurred with this recommendation.

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?**

GAO has not analyzed whether disclosure of covered entities' arrangements with contract pharmacies and TPAs would improve 340B oversight. Covered entities are required to provide HRSA with copies of their pharmacy contracts upon request and HRSA obtains copies of contracts for covered entities that are audited. In addition, in fiscal year 2017, HRSA began collecting contracts for 5 percent of new contract pharmacy registrations. According to HRSA officials, the agency reviews these contracts to check that (a) there is a written contract in place, (b) that the date of the contract is prior to the pharmacy being registered with HRSA, (c) the contract lists which covered entity sites are covered, and (d) the contract is signed by officials from both the covered entity and the pharmacy. HRSA guidance does not contain required contract provisions or dictate the types of financial arrangements covered entities may have with their contract pharmacies. HRSA guidance gives covered entities the discretion to negotiate contract provisions and HRSA officials noted that they consider such arrangements to be business decisions between the parties.

Regarding the contracts between covered entities and TPAs, HRSA officials indicated that they may request a contract with a TPA if an audit revealed evidence that the TPA contract was directly involved in issues of diversion or duplicate discounts. However, officials noted that even if the TPA's process was the cause of a compliance issue, HRSA may not need to see the actual contract and there were no instances when HRSA has requested a copy of the TPA contract. Additionally, HRSA also considers the financial arrangements between covered entities and TPAs to be a business decision between the two parties.

<u>The Honorable Richard Hudson</u>

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?

Under HRSA guidance, covered entities may contract with an outside pharmacy, referred to as a contract pharmacy, to dispense 340B drugs on its behalf. Covered entities that choose to have contract pharmacies are, according to HRSA guidance, required to have a written contract in place with each pharmacy through which it intends to dispense 340B drugs. Covered entities are also required to register with HRSA the names of each of the pharmacies with which they contract. Thus, covered entities that want to contract with Amazon or a similarly situated online company to dispense 340B drugs would need to have a written contract with such companies and register the names of the companies with HRSA.

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?**

   We defer to Congress on the policy question of whether covered entities and pharmacies should be prohibited from charging patients with dispensing fees 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?**

   A May 2014 federal district court ruled that the agency had not been granted broad rulemaking authority to carry out the provisions of the 340B Program. The court found that the within section 340B of the Public Health Service Act, Congress authorized rulemaking in three places: (1) the establishment of an administrative dispute resolution process, (2) the methodology for calculating of 340B ceiling prices, and (3) the imposition of monetary civil sanctions. *See Pharm. Research & Mfrs. of Am. v. United States HHS*, 43 F. Supp. 3d 28, 41 (D.D.C. 2014).

<u>The Honorable Chris Collins</u>

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?**

The statute authorizing the 340B Program does not dictate how covered entities should use the revenue generated from 340B drugs or require discounts on the drugs to be passed along to patients. The decision on whether covered entities should be required to share the 340B discount with patients is a policy question, and we defer to Congress on making such a decision.

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?**

   As noted in your question, 13 of the 29 contracts between covered entities and contract pharmacies that we reviewed included provisions for the covered entity to pay the contract pharmacy a fee based on the percentage of the revenue generated by each 340B prescription dispensed to eligible patients. These fees only applied to prescriptions dispensed to patients with insurance. We did not assess what, if any, incentives this fee structure creates for the covered entity or the contract pharmacy. However, we did issue a report in June 2015 that compared spending for Medicare Part B drugs, including oncology drugs, at certain hospitals that participated and did not participate in the 340B Program. In that report, we found that, in both 2008 and 2012, per beneficiary Medicare Part B drug spending, including oncology drug spending, was substantially higher at certain 340B hospitals than at non-340B hospitals. This indicated that, on average, beneficiaries at these 340B hospitals were either prescribed more drugs or more expensive drugs than beneficiaries at the other hospitals analyzed. We concluded that because Medicare pays hospitals at set rates for Part B drugs regardless of their costs for acquiring them, there was a financial incentive at hospitals participating in the 340B program to prescribe more drugs or prescribe more expensive drugs to Medicare beneficiaries.

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 Department of Health and Human Services (HHS) has stated that it would face challenges with issuing guidance on 340B policy matters in cases where HHS's enforcement authority is limited, and noted that HRSA does not have explicit regulatory authority to issue regulations on most aspects of the 340B Program. Additionally, HRSA expressed concern that implementing some of our recommendations would create significant burden on covered entities and additional work for the agency. As noted in our report, it is unclear how implementing our recommendations would create significant burden for covered entities as they call for documenting and providing HRSA with information on actions the covered entities are already supposed to be taking. Additionally, while we agree that implementing our recommendations may create additional work for HRSA, we continue

to believe that this work is necessary for HRSA's oversight to be effective and could reduce the need for re-audits of covered entities, which are burdensome in terms of costs and time for both covered entities and HRSA.

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?**

    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?**

HRSA does not collect data on the extent to which covered entities provide discounts on 340B drugs dispensed to low-income patients; nor does the agency have information on the financial arrangements between covered entities and contract pharmacies or third-party administrators. As a result, to answer the research questions for our June 2018 report, we selected samples of covered entities, and contracts between covered entities and contract pharmacies, from which to obtain information. Covered entities and contracts were selected to obtain variation on a variety of factors, including the type of covered entity and geographic location. As noted in the report, these were nongeneralizable samples; thus, our findings cannot be generalized to other covered entities or contract pharmacies. Rather, the findings are intended to provide illustrative examples to provide Congress with more insight into covered entities and their use of contract pharmacies.

2. **Dr. Draper, of the recommendations made by GAO in this report, what are the top two recommendations the Committee should consider most closely?**

We believe that all seven recommendations made in GAO's June 2018 report are important for improving HRSA's oversight of the 340B Program and mitigating the risk of noncompliance. In particular, we would call the Committee's attention to our two recommendations related to the prohibition on duplicate discounts. Specifically, we recommended that the Administrator of HRSA:

- issue guidance to covered entities on the prevention of duplicate discounts under Medicaid managed care, working with CMS as HRSA deems necessary to coordinate with guidance provided to state Medicaid programs; and
- incorporate an assessment of covered entities' compliance with the prohibition on duplicate discounts, as it relates to Medicaid managed care claims, into its audit process after guidance has been issued and ensure that identified violations are rectified by the entities.

As noted in our June 2018 report, the potential for duplicate discounts related to Medicaid managed care has existed since 2010 when manufacturers were required to pay Medicaid rebates under managed care. HRSA officials told us that they do not assess the potential for duplicate discounts in Medicaid managed care as part of their audits because they have yet to issue guidance as to how covered entities should prevent duplicate discounts in Medicaid managed care. However, federal law directs HRSA to develop detailed guidance describing

methodologies and options for avoiding duplicate discounts. Currently, there are more Medicaid enrollees, prescriptions, and spending for drugs under managed care than fee-for-service. As such, until HRSA develops guidance and includes an assessment of the potential for duplicate discounts in Medicaid managed care as part of its audits, the agency does not have assurance that covered entities' efforts are effectively preventing duplicate discounts related to the majority of the Medicaid program.