April 30, 2015

The Honorable Joseph R. Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
House of Representatives

Dear Chairman Pitts,

This letter responds to your request that we address questions submitted for the record related to the March 24, 2015 hearing entitled Examining the 340B Drug Pricing Program. GAO's responses to these questions are enclosed.

If you have any questions about these responses or need additional information, please contact Debra A. Draper at draperd@gao.gov or call (202) 512-7114.

Sincerely yours,

Debra A. Draper
Director, Health Care

Enclosure
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. 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?

The Health Resources and Services Administration (HRSA) had been preparing its regulations after GAO issued a report in 2011 which included recommendations that the agency finalize new, more specific guidance on the definition of a 340B patient, and issue guidance to further specify program eligibility criteria for certain hospitals. GAO recommendations generally provide flexibility to audited agencies in terms of implementation. Our recommendations did not require HRSA to issue such guidance through rulemaking.

In addition, GAO does not track instances where agencies have been found by a court to have exceeded their rulemaking authority. However, in ruling that HRSA’s orphan drug rule exceeded the scope of its statutory rulemaking authority, the district court relied upon several cases that similarly held that Congress had not authorized agency rulemaking in specific areas. We bring to your attention three cases that the court discussed at length in its May 2014 opinion:

- In *Gonzales v Oregon*, 546 U.S. 243 (2006), the United States Supreme Court held that an interpretive rule issued by the U.S. Attorney General was not authorized by the * Controlled Substances Act*, in part, because the act did not grant the Attorney General broad authority to promulgate rules, but instead specified two areas where he had rulemaking power.

- In *Amalgamated Transit Union v Skinner*, 894 F.2d 1362 (D.C. Cir. 1990), the Court of Appeals for the D.C. Circuit vacated a Department of Transportation rule requiring mass transit grant recipients to implement an anti-drug safety program. The court found that the Urban Mass Transportation Act only authorized the agency “to investigate safety hazards . . . in a manner that requires case-by-case development of local solutions to those hazards,” not to engage in rulemaking.

- In *Motion Picture Association of America v. FCC*, 309 F.3d 796 (D.C. Cir. 2002) the Court of Appeals for the D.C. Circuit vacated a proposed FCC rule that would have required the use of video description technology to enhance TV watching for hearing and visually impaired persons. The court found that the proposed video description regulation exceeded the scope of FCC’s rulemaking under the *Telecommunications Act of 1996*. Whereas the Act required FCC to issue regulations for closed captioning technology, it only required FCC to prepare a report for Congress on the use of video description technology.

In responding to GAO’s request for updated information with respect to the March 24, 2015 testimony, HRSA officials told us that the agency planned to issue guidelines in 340B program
areas for which it does not have explicit rulemaking authority. At the same time, these officials noted that having “clear legislative authority for 340B rulemaking authority would be most effective in facilitating HRSA’s oversight and management of the 340B Program. Rulemaking authority would also allow HRSA to better ensure program integrity so that the program operates as effectively and efficiently as possible.”

2. GAO cites the increase in hospital participation and the lack of clear guidance in a patient definition as the key reason for risks associated with drug diversion under the program. Did GAO track the scope or end of drug diversion occurring in the projects it examined—in other words, do we know if prescription drugs were improperly distributed for illicit purposes?

In our prior work, GAO did not track whether, or the extent to which, drug diversion was occurring under the 340B program. We identified situations where the risk of drug diversion may be higher than others, such as at contract pharmacies and hospitals.¹ For example, we reported that the risk of diversion was greater at hospitals because hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed and must ensure that inpatients do not receive 340B drugs (only outpatients are eligible). In addition, we reported that hospitals tend to have more complex contracting arrangements and organizational structures than other entity types, noting that in hospitals, 340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. In light of this and other factors, diversion may be harder to detect in hospital settings. We recommended that the HRSA conduct audits of covered entities to deter potential diversion. In response to our recommendation, HRSA has conducted annual audits of covered entities and identified instances of violations related to drug diversion.

3. Around 20 percent of covered entities are private, non-profit hospitals that become eligible, in part, through their DSH percentage. However, these “DSH hospitals” account for over 80 percent of the discounts under the program. At the same time, recent reports question whether the use of the DSH percentage as eligibility criteria for these private, non-profit hospitals is appropriate in the first place. For example, MedPAC has noted “little evidence of a relationship between the DSH payments hospitals receive and the amount of uncompensated care they provide[,]” which raises doubts about the 340B program’s reliance on DSH for eligibility purposes. Are there options that would establish a better charity care proxy for hospital entry into the program? What criteria that might better reflect a hospital’s uncompensated care that would justify entry into the program?

Hospital eligibility criteria include minimum Medicare disproportionate share adjustment (DSH) percentages for most hospital types, as well as other requirements intended to ensure that they perform a government function to provide care to the medically underserved. The law does not specify why the DSH adjustment percentage is used as criteria. The DSH adjustment percentage identifies hospitals that treat a significantly disproportionate number of low-income Medicare and Medicaid patients. If this is being used as a proxy to identify hospitals that provide more uncompensated care than other hospitals, then the questions raised by MedPAC about

the relationship between DSH payments and the amount of uncompensated care would raise questions about the appropriateness of DSH adjustment percentage for this proxy.

If Congress wishes to identify eligibility criteria that better ensure that certain hospitals participating in the program are those that provide more uncompensated care or more charity care than other hospitals, then it could consider using either the uncompensated care or charity care values that are reported in hospitals’ Medicare cost reports as a basis for eligibility. However, questions have been raised about those measures as well. For example, the uncompensated care values include both charity care and bad debt. Some researchers contend that the bad debt measure could reflect the ability of a hospital to collect payments from patients and not whether or not those patients are able to afford the payments. The charity care measure is a more targeted measure; however, this is a relatively new measure included on the Medicare cost reports and questions have been raised about potential variation in how hospitals define and calculate charity care.

In addition, because the current eligibility criteria for hospitals also includes components related to ensuring that hospitals perform a government function to provide care to the medically underserved, Congress could consider the extent to which certain hospitals should qualify based solely on criteria related to the provision of these types of services. For example, in our 2011 report, we noted that there is no established definition of a safety net hospital. Some researchers have argued that this definition should include factors such as the disproportionate provision of critical services that are either too expensive or unprofitable for other hospitals to provide, such as trauma care.2

4. 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 Congress on this policy proposal?

The pros and cons of reducing Medicare Part B payments for 340B entities depends upon Congress’s goals for the 340B Program. Currently the program is structured so that participating entities financially benefit from the difference between the discounted price they pay to acquire 340B drugs and the amount that payers, including Medicare, reimburse the entities for these drugs. The 340B program generates revenue for participating entities and there is no requirement within the 340B program on how they use that revenue, or for participating entities to pass along to Medicare or its beneficiaries any of the savings associated with the 340B drugs. Whether such a requirement would be appropriate depends upon Congress’s goals for the 340B program.

Reducing Medicare payments for 340B drugs or requiring that participating entities pass along some or all of the discounts to Medicare beneficiaries, would produce savings for the Medicare program and its beneficiaries, but it would also likely substantially reduce the revenues that

entities generate from the 340B program. Specifically, in our 2011 report, we found that among the 340B entities that generated revenue through the program, most reported that they generated more 340B revenue from patients with private insurance and Medicare compared to other payers. However, a few of these covered entities reported that their ability to generate 340B revenue from private insurers was decreasing because some insurers were reducing contracted reimbursement rates for drugs based on the entity’s status as a 340B provider. Reducing Medicare Part B payments for 340B drugs further limit entities’ ability to generate revenues through the program.

Congress could also consider whether any reductions in Medicare Part B payment rates would apply to all types of 340B entities or to a subset of the entity types. For example, Congress might consider whether the benefit of using the program as a financing mechanism should only apply to certain types of entities. Entities generally become eligible for the program by being one of six hospital types or by receiving one of 10 federal grants. Hospitals eligible for the program include certain DSH hospitals, children’s hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals. Federal grantees include clinics that offer primary and preventive care services, such as Federally Qualified Health Centers, family planning clinics, and clinics that target specific conditions or diseases that raise public health concerns or are expensive to treat, such as hemophilia treatment centers. Our interviews with a small nongeneralizable sample of 340B entities for our 2011 report found that some were more reliant on 340B revenue than others. For example, one hemophilia treatment center reported that 340B revenue accounted for about 97 percent of its total budget and was used to support all of its program operations. Some other entities reported that 340B revenue represented a much smaller share of their operating budgets.

The Honorable Tim Murphy

1. The September 2011 GAO report (Drug Pricing: Manufacturer Discount in the 340B Program Offers Benefits, But Federal Oversight Needs Improvement) states, “Clinics and other sites affiliated with a hospital, but not located in the main hospital building, are eligible to participate in the 340B program if they are an integral part of the hospital, which HRSA has defined as reimbursable sites on the hospital’s most recently filed Medicare cost report.” (Page 10) Does this mean that a hospital or hospital system could acquire a 340B eligible clinic and purchase their outpatient drugs at the 340B discounted price through these clinics?

   a. In the GAO’s review of the 340B program, did you identify any examples of hospitals or hospital systems using the program in this manner?

   b. Would you consider the use of the program in this manner consistent with the original intent of the program?

In order for a hospital to be eligible for the 340B Program, it must meet the 340B hospital eligibility criteria defined in statute. For example, some hospitals are eligible based on having a DSH adjustment percentage of 11.75 or greater and meeting other statutory criteria. Owning a clinic that is eligible for the 340B program does not make a hospital eligible for the 340B Program. A freestanding clinic that participates in the program based on its federal grantee status can be acquired by a non-340B hospital and continue to be eligible for and participate in
the 340B program. While patients of those clinics would be eligible for 340B discounted drugs, that eligibility does not transfer to all of the hospital’s outpatients.

The section of our previous report that you cited in your question pertains to a different situation—that of a 340B hospital acquiring clinics that are not eligible for the 340B Program.\(^3\) Per HRSA’s 1994 program guidelines and clarifying guidance issued in 2012, a 340B hospital can purchase outpatient clinics that can then be considered an integral part of that hospital. As an integral part of the hospital, a hospital outpatient clinic would be eligible for 340B drug discounts if it is a reimbursable facility and is included on the 340B hospital’s Medicare cost report whether or not it is located in the main hospital building. When a clinic is acquired by a 340B hospital, 340B discounted drugs can be used for patients of that clinic. An example would be an oncology clinic that is acquired by a 340B hospital. Although a freestanding oncology clinic would not be eligible for the 340B program, if it is acquired by a 340B hospital, considered a reimbursable facility, and included on the hospital’s Medicare cost report, 340B discounted drugs could be used for patients of that clinic.