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November 27, 2019

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS–10709, Hospital Survey for Specified Covered Outpatient Drugs; Agency Information Collection Activities: Proposed Collection; Comment Request (Vol. 84, No. 189), September 30, 2019.

Dear Ms. Verma:

On behalf of our nearly 2,000 340B member hospitals, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) notice to undertake a survey of all hospitals that participate in the 340B Drug Pricing Program in order to collect actual acquisition costs for specified covered outpatient drugs.

The AHA has significant concerns with the intent and design of the 340B hospital survey, and we request that CMS withdraw it. CMS has stated, in the notice as well as in the final rule for the calendar year (CY) 2020 Medicare outpatient prospective payment system (OPPS), that the agency intends to use the survey results not only in future Medicare Part B 340B payment policy but also as the possible basis for a remedy related to ongoing litigation.¹ The AHA has long argued that CMS's Medicare Part B payment policy imposes such drastic reductions in the payment rate for 340B drugs that it severely undermines the benefits of the 340B program.² The magnitude of the cuts for OPPS payment years CYs 2018-2020 has compromised 340B hospitals' ability to establish and continue the operation of programs designed to improve access to services for their patients – which is the very purpose of the 340B program.

Congress created the 340B program to permit hospitals serving vulnerable communities, such as low-income and uninsured patients, “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³ For more than 25 years, the 340B program has been critical

¹ <https://www.govinfo.gov/content/pkg/FR-2019-09-30/pdf/2019-21120.pdf>; <https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf>

² <https://www.aha.org/legal-documents/2019-09-24-aha-associations-hospitals-reply-brief-government-appeal-340b>

³ <https://www.hrsa.gov/opa/index.html>

in helping hospitals expand access to comprehensive health care services, including access to lifesaving prescription drugs, in vulnerable communities across the country, including low-income and uninsured individuals in these communities. Given the rapid escalation in the cost of pharmaceuticals, the 340B program provides critical support to help hospitals' efforts to build and promote healthy communities. CMS's plan to collect actual acquisition cost data from *only* 340B hospitals confirms the agency's intent to continue down its policy path for 340B hospitals and their patients.

The following comments address specific issues about the survey approach and design, including: the statutory requirements for conducting a survey; the burden on hospitals in submitting the survey data; the challenges hospitals face in sharing drug prices; and other issues related to drug pricing and the 340B program.

Statutory Requirements. We have several concerns regarding CMS's hospital acquisition cost survey approach and whether it conforms to the statutory requirements established by Congress. The Medicare statute provides CMS with two options for reimbursing covered outpatient drugs.⁴ Under 42 U.S.C. Sec.1395l(t)(14)(A)(iii), CMS must base payment rates on the average acquisition costs, but only if the hospital acquisition cost survey data meets the specifications spelled out in paragraph (t)(14)(D). The statutory language here requires that the survey "...have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug."⁵ The statutory language is clear that the survey should be a large enough sample size of hospitals to generate a statistically significant estimate. However, CMS states that it will not be using any statistical methodology or sample selection for the survey. It appears that CMS will be administering the survey to all 340B hospitals and believes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute. We have serious concerns about the statistical validity of this approach because there are no selection criteria. Also, CMS does not provide enough information to evaluate whether the results would be biased on the basis of who responds to the survey.

In addition, under the statute, CMS may not limit the survey to a subset of hospitals. Congress in (t)(14)(C)(ii) of the statute directs CMS to collect "hospital acquisition cost for each specified covered outpatient drug for use in setting the payments rates..." Nowhere in the statute does Congress give CMS the authority to collect acquisition cost data from only a specific subset of all hospitals. While Congress does state in (t)(14)(A)(iii) that CMS could vary hospital OPPS payment by hospital group – based on the data gleaned from the hospital acquisition cost survey – the potential variation is premised on the requirement that the survey include all hospitals, not just a subset of hospitals. In other words, for purposes of surveying hospitals, Congress does not distinguish between hospitals paid under OPPS based on their 340B status and those

⁴ <https://www.aha.org/legal-documents/2019-09-24-aha-associations-hospitals-reply-brief-government-appeal-340b>

⁵ <https://www.law.cornell.edu/uscode/text/42/1395l>

that are not. **Therefore, CMS’s survey design and approach does not meet the statutory requirements when it specifies that only 340B hospitals are required to complete the survey. For this reason alone, CMS should not conduct the survey as currently constituted.**

Burden on 340B Hospitals. There appear to be inconsistencies in the information and instructions found in the notice published in the *Federal Register* and the supporting documentation, Supporting Statements A and B, which may cause confusion among 340B hospitals and other stakeholders. In the notice, CMS states that it would require “certain” hospitals enrolled in the 340B program in the last quarter of 2018 and/or the first quarter of 2019 to complete the survey. However, there is some confusion around exactly which 340B hospitals and how many are expected to complete the survey. That is, the *Federal Register* survey notice and the Supporting Statement – Part A state that all 340B hospitals, which would include critical access hospitals, children’s hospitals, freestanding cancer hospitals and other rural hospitals, would be required to complete the survey. The survey’s Supporting Statement – Part B, however, suggests only those 340B hospitals paid under OPDS are required to complete the survey. The inconsistency between the published notice and the supporting documentation is confusing and may lead to less meaningful responses.

For those hospitals required to complete the survey, each would be required to list, by each provider-based department of the hospital enrolled in the 340B program, the following information:

- Healthcare Common Procedure Coding System (HCPCS) code for each specified covered outpatient drug;
- Drug name and a short descriptor;
- Dosage unit for each drug;
- Average 340B price for the fourth quarter of calendar year 2018; and
- Average 340B price for the first quarter of calendar year 2019.

The agency estimates in the *Federal Register* notice that for the 761 respondents that complete the survey, they would submit approximately 46,610,448 survey responses, which would take about 33,500 hours to complete. On face value, this appears to be a gross underestimation of the burden 340B hospitals would bear in both gathering the data elements to adequately respond to the survey and formatting that data in the manner required by CMS. In addition, here is another example where the supporting documents are not consistent with the published notice. That is, in Supporting Statement – Part B, CMS notes that it expects 1,338 340B hospitals to respond, again making it challenging for the public to assess the predicted impact of the survey and its burden.

In any event, the burden of reporting acquisition cost data remains a concern. The Government Accountability Office (GAO), in its 2006 report to Congress about the lessons learned when conducting its hospital acquisition cost survey, stated that the

survey “created a considerable burden for hospitals.” In addition, GAO reported that hospitals told the agency that, “to submit the required price data, they had to divert staff from their normal duties, thereby incurring additional costs.”⁶ It is important to note that 340B hospitals are a diverse group ranging from small rural hospitals to large academic centers that care for significant numbers of low-income patients. All of these 340B hospitals already are shouldering significant costs for staff, software, health information and inventory management systems to ensure they are compliant with the rules and requirements of the 340B program. In addition, 340B hospitals are operating on thin operating margins, such that these additional costs, in terms of staff time and resources, which will need to be diverted from the primary mission of the 340B program. For our financially struggling 340B hospital members in urban and rural settings, the survey burden may be insurmountable. **The AHA urges CMS to conduct a more thorough assessment of the “considerable burden for hospitals” before moving forward with the survey.**

Challenges in Sharing and Determining Drug Prices. 340B hospitals typically purchase their 340B drugs through wholesalers – for example, McKesson Pharmaceuticals – or directly from the drug manufacturer. These purchasing arrangements are contractual agreements. The wholesaler contracts, in particular, typically have strict non-disclosure provisions. It is our understanding that they may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract. These non-disclosure provisions may make it impossible for 340B hospitals to share the data necessary to complete the survey. In addition, the survey requests that hospitals report drug prices at the HCPCS unit level price versus the invoiced price, which will require significant additional work on the part of the hospitals to format the data in the requested manner. Lastly, because drug prices change frequently, it is not clear that the two quarters of data CMS is requesting will represent meaningful acquisition costs for 340B drugs considering the rapid fluctuation in the drug prices.

The AHA continues to believe that CMS’s OPPS 340B payment policy is so disruptive that it will severely undermine the 340B program. The survey of 340B hospital acquisition cost data is another tool for CMS to use to accelerate its efforts to curtail the program. CMS should reconsider, and instead support, the role that the 340B program plays in allowing hospitals to better serve their patients and communities. **The agency should abandon its damaging OPPS 340B payment policy and withdraw this survey.**

We appreciate your consideration of these comments. Please contact me, if you have questions or feel free to have a member of your team contact Molly Collins Offner, director for policy, at mcollins@aha.org or Roslyne Schulman, director for policy, at rschulman@aha.org.

⁶ <https://www.gao.gov/assets/250/249967.pdf>

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Page 5 of 5

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President
Government Relations and Public Policy