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March 9, 2020

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. 85, No. 26), February 7, 2020.

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 (SCODs). This notice updates CMS's previous notice, including by further compressing the timeframe for which 340B hospitals must respond to the survey.

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 both in future Medicare Part B 340B payment policy and 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 and the 340B statute.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, and the federal district court in Washington, D.C. has agreed that these cuts are impermissible under federal law. CMS's plan to collect actual acquisition cost data from *only* 340B hospitals suggests that the agency intends to continue down a policy path to abrogate the program, undermining the 340B statute.

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>

Congress created the 340B program to enable hospitals serving vulnerable communities, such as those with high rates of 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 to helping hospitals expand access to a wide range of health care services, and is one of the few federal policies that addresses the skyrocketing cost of prescription drugs used for hospital patients.**

In addition to AHA’s overall objections to the design and use of survey data identified below, AHA also believes that use of survey data collected for use in rate-setting under subclause II of 42 U.S.C. Sec. 1395l(t)(14)(A)(iii) to retroactively justify 2018-20 rates established under an entirely different authority, subclause I of 42 U.S.C. Sec. 1395l(t)(14)(A)(iii), is a violation of the Medicare Act and the Administrative Procedure Act.

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, and, based on what CMS has disclosed about the survey, we believe that it does not conform 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 taking into account hospital acquisition cost survey data specified by the statute, or, if hospital acquisition cost data are not available, the average price for the drug as calculated and adjusted by the Health and Human Services Secretary. With regard to the first option, reimbursement can only be based on the average acquisition costs as acquired through survey data if the survey meets the specifications spelled out in section (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 Despite clear statutory language, CMS states in the notice that it will not be using any statistical methodology or sample selection for the survey. It appears that CMS instead intends to administer the survey to all 340B hospitals and hopes that the response rate will be high enough to yield statistically valid results. We do not believe that this approach complies with the statute, as the agency cannot assure the statistical validity of this approach because CMS has not identified a statistically valid sample and as it acknowledges it will not be able to assure that all 340B hospitals respond to the survey. In addition, CMS does not provide enough

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

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>

information to evaluate whether the results would be biased on the basis of who responds to the survey.

Another question raised by CMS's survey design is that it may not yield the true acquisition cost of each drug as required by the statute. This is because the survey instructions ask hospitals to report actual acquisition cost at the Healthcare Common Procedure Coding System (HCPCS) level, and states that reporting at the National Drug Code (NDC) level is optional. NDCs within a HCPCS level can vary widely in price, so providing acquisition cost data at the HCPCS level may not accurately reflect the true acquisition cost of each NDC within that HCPCS level. The statute in section (t)(14)(D) is clear that the survey must be designed to collect data on the average hospital acquisition cost for each SCOD. As a result, we believe that CMS's survey design does not meet the requirements set forth in the statute.

In addition, under the statute, in establishing reimbursement rates for outpatient drugs, CMS must either use average acquisition costs based on a survey that meets the requirements of the statute (subclause I of section 1395l(t)(14)(iii)) or average price based on various statutory provisions (subclause II of section 1395l(t)(14)(iii)). CMS may not use subclause I for some hospitals and subclause II for others, and thus it 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 use of the authority in subclause I to establish the rate for all hospitals and thus the survey must 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 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. Hospitals required to complete the survey would be required to list the following information:

- HCPCS code for each specified covered outpatient drugs;
- 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 1,338 respondents that complete the survey it would take approximately 64,224 hours to complete at a total

cost of approximately \$4.9 million. The staff and technology resources that would be necessary to complete this survey suggest that the agency has underestimated the burden and cost 340B hospitals would bear in responding.

The government has previously acknowledged the burden such a survey would impose on hospitals. 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.” The 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 Through this notice, CMS would exacerbate the demands on hospitals by compressing the timeframe for their responses to only three weeks, a timeframe that is untenable for most 340B hospitals. It is important to note that 340B hospitals are a diverse group ranging from small rural hospitals to large academic centers. All of these 340B hospitals already are shouldering significant costs for staff and health information and inventory management systems to ensure they are compliant with the rules and requirements of the 340B program. In addition, many 340B hospitals are operating on thin operating margins, such that these additional costs, in terms of staff time and resources, would likely need to be diverted from the primary mission of the 340B program. For our financially struggling 340B hospital members – whether 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 or directly from the drug manufacturer. These purchasing arrangements are contractual agreements. The wholesaler contracts, in particular, typically have strict non-disclosure provisions to protect against anticompetitive pricing behavior. It is our understanding that these provisions may prevent 340B hospitals from sharing any drug pricing information with any entity not party to the contract and therefore make it impossible for 340B hospitals 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 would 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.

CONCLUSION

CMS’s OPPS 340B payment policy is unlawful and will severely undermine the 340B program at the detriment of vulnerable communities and place undue burden and cost on hospitals. This survey of 340B hospital acquisition cost data is part of another attempt by the agency to curtail the program. CMS should reconsider, and instead

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

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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.

Sincerely,

/s/

Ashley Thompson
Senior Vice President, Public Policy Analysis and Development