AMERICA'S ESSENTIAL HOSPITALS

November 27, 2019

William Parham III
Director
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Ref: CMS-10709: Agency Information Collection Activities: Proposed Collection; Comment Request

Dear Director Parham:

America's Essential Hospitals appreciates the opportunity to submit comments in response to the Centers for Medicare & Medicaid Services' (CMS') notice of proposed information collection. We are deeply concerned that the proposed drug acquisition cost survey would impose excessive burden on hospitals participating in the 340B Drug Pricing Program and would raise many operational challenges. It would single out these hospitals—hospitals that already operate on narrower margins than others and invest substantial resources into program compliance—with additional reporting requirements on top of the existing, resource-intensive obligations they adhere to under the 340B program.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all, including the vulnerable. Filling a vital role in their communities, our more than 300 member hospitals provide a disproportionate share of the nation's uncompensated care and three-quarters of their patients are uninsured or covered by Medicare or Medicaid. Our members provide state-of-the-art, patient-centered care while operating on margins one-fifth that of other hospitals—1.6 percent on average compared with 7.8 percent for all hospitals nationwide.[1] Essential hospitals' commitment to serving all people, regardless of income or insurance status, and their diverse patient mix pose unique challenges. A disproportionate number of

[1] Clark D, Roberson B, Ramiah K. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2017 Annual Member Characteristics Survey.* America's Essential Hospitals. April 2019. www.essentialdata.info/. Accessed November 7, 2019.

AMERICA'S ESSENTIAL HOSPITALS
401 Ninth St NW Ste 900
Washington DC 20004
t: 202 585 0100
f: 202 585 0101
e: info@essentialhospitals.org

their patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Ten million people in essential hospital communities have limited access to healthy food, and nearly 24 million live below the poverty line.[2] Essential hospitals are uniquely situated to address these social determinants of health and are committed to serving these vulnerable patients. These circumstances, however, compound essential hospitals' challenges and strain their resources, necessitating flexibility to ensure they are not unfairly disadvantaged for serving the nation's most vulnerable patients and can continue to provide vital services in their communities.

By enacting the 340B program, Congress intended to allow covered entities to "stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."[3] Put simply, Congress wrote the law specifically to allow qualifying hospitals to retain the 340B savings so they could serve their vulnerable communities. Savings from the 340B program are indispensable to hospitals operating on narrow margins. As the Department of Health and Human Services (HHS) works to slow the rising cost of prescription drugs, we urge the agency to keep in mind the needs of the nation's vulnerable patients and the hospitals that serve them. CMS' inequitable policy to reduce Part B drug payments to hospitals with the most vulnerable patients already has severely impacted essential hospitals since it was implemented in 2018. It undermines these providers' ability to offer heavily discounted drugs to patients in the face of rapidly increasing drug prices. A continuation of payment rates below 106 percent of average sales price (ASP)—whether tied to acquisition cost or to 77.5 percent of ASP—will be devastating to hospitals with the lowest margins as they work to care for the most vulnerable patients.

We are concerned that CMS has not considered the administrative burden of the proposed information request or its authority to collect this information in the proposed manner. In our detailed comments below, we urge CMS to withdraw its proposed information collection request, given the agency has not fully evaluated both its authority to conduct this survey and the true scope of the operational complexity associated with this request.

1. CMS' proposed data collection exceeds its authority under the Medicare statute.

CMS' proposed collection of drug acquisition costs—through a survey to be completed only by 340B hospitals—violates the Medicare statute's prescribed methodology for collecting acquisition costs for specified covered outpatient drugs (SCODs). In the notice, CMS states it will collect acquisition cost through a "hospital survey for SCODs." The agency notes that it is only directing 340B hospitals to report acquisition costs through the survey; hospitals not in the 340B program will not be required to report their acquisition costs because CMS believes ASP data is "an adequate measure of the drug acquisition costs" of these hospitals. The selective collection of drug acquisition

[2] Ibid.
[3] H.R. Rep. No. 102-384, pt. 2 (1992).

costs based on an arbitrarily selected hospital characteristic (in this case participation in the 340B program) conflicts with the acquisition cost collection methodology that Congress outlined for CMS in the Medicare statute.

The provision of the Social Security Act which authorizes CMS to collect drug acquisition costs, section 1833(t)(14)(D), first required that the Comptroller General of the Government Accountability Office (GAO) conduct a hospital acquisition cost survey in 2004 and 2005 to determine the hospital acquisition cost for each SCOD. Then, CMS is to "conduct periodic subsequent surveys to determine the hospital acquisition cost for each [SCOD] for use in setting the payment rates under subparagraph (A)." The survey requirement is for the collection of hospital acquisition costs of each SCOD—there is no reference to only 340B drugs or 340B hospitals. More significantly, the Medicare statute has specific requirements about the scope of the survey, requiring that the surveys be conducted using a "large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each [SCOD]." Hospitals in the 340B program account for only a portion of all Outpatient Prospective Payment System (OPPS) hospitals. CMS estimates that 1,338 hospitals would fill out the survey, which is only about one-third of the more than 3,600 hospitals paid under the OPPS.

It is worth noting that hospitals not participating in the 340B program can benefit from additional discounts that allow them to purchase drugs at prices significantly below the list price. Hospitals that are part of large systems leverage their size to procure volume discounts. Non-340B hospitals can use group purchasing organizations—which 340B hospitals are statutorily prohibited from using for 340B drugs—to negotiate sizable discounts on their drugs. For CMS to gather data on and pay hospitals based on acquisition cost, it must collect information for all hospitals to capture the different types of discounts that can affect acquisition cost, which it does not propose to do in this information collection request.

Because the survey only focuses on one type of hospital, it does not satisfy statutory sampling requirements and, ultimately, would not accurately capture average acquisition costs of all OPPS hospitals. **Therefore, CMS should withdraw its proposed information collection, which exceeds its statutory authority because it is contrary to the Medicare statute.**

2. **CMS' information collection would be burdensome for hospitals and involve time and resources far exceeding CMS' estimates.**

CMS' acquisition cost survey would be administratively burdensome for hospitals and for the agency. This administration has emphasized the importance of reducing provider burden and focusing on patient care, as exemplified in its Patients Over

Paperwork initiative.[4] America's Essential Hospitals commends the administration for its attempts to reduce regulatory and administrative burden through such initiatives. CMS' proposed information collection, however, would be a setback to the agency's efforts to reduce provider burden. The survey is operationally complex, is bound to increase regulatory burden, and will strain hospital systems and staff resources. **We urge CMS to consider the administrative burden its proposed information collection would impose on essential hospitals.**

As part of Paperwork Reduction Act requirements, CMS estimates that the survey would take 48 hours for the average hospital to complete. CMS further notes that it has "taken steps to mitigate the burden of the survey" and that producing the required information would not be burdensome because 340B participation requires that hospitals maintain records to "ensure that such acquired drugs are used for eligible patients."[5] However, records required for 340B compliance and audits do not require hospitals to collect 340B acquisition cost data. In fact, hospitals do not have 340B drug acquisition costs readily available in their systems. The time required to extract this information, calculate average acquisition costs, and produce the data in the format CMS requires, would be substantially more than the 48 hours CMS estimates. Hospitals have noted that these burdensome requests would necessitate the diversion of existing staff from their regular duties or the hiring of additional staff. Further explanation of why the request is particularly burdensome is outlined below.

First, hospitals likely will have to obtain this information from a third party, such as their drug wholesaler. Hospitals enter into detailed contractual agreements with their wholesalers governing the types of information they can share with other parties. The data possessed by the wholesaler are confidential and proprietary, and hospitals would have to evaluate these contracts to ensure they do not require modification to allow them to share the information with CMS. In addition to the proprietary nature of the data, many wholesaler agreements place limits on the time period for which acquisition cost data can be downloaded. Requesting older data from the wholesaler that do not fall within the look-back period is an additional burden that requires the hospital to submit a special request to the wholesaler.

Second, even if hospitals can obtain permission from their wholesaler to retrieve and share acquisition cost data, the data provided by the wholesaler will not be in the format CMS requests. CMS proposes to require that hospitals report average acquisition cost for two quarters (the fourth quarter of calendar year 2018 and the first quarter of calendar year 2019) for all SCODs with status indicator K or G, by Healthcare Common Procedure Coding System (HCPCS) code. Once a hospital can download the information from its wholesaler, hospitals will have to cross-reference the list provided

[4] Verma S. Remarks delivered at the Health Care Payment Learning and Action Network Fall Summit. October 30, 2017. https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-30.html. Accessed November 6, 2019.
[5] Centers for Medicare & Medicaid Services. Supporting Statement—Part A. Hospital Survey for Specified Covered Outpatient Drugs (SCODs). CMS-10709; OMB 0938-New.

to find drugs with status indicators K or G. The data hospitals receive from their wholesaler will be identified by National Drug Codes (NDCs), not by HCPCS code. Each HCPCS billing unit corresponds to a specified unit of measure and amount for a given drug, which usually differs from the package size and dosage corresponding to an NDC for the same drug. There often are multiple NDCs that match a given HCPCS code, but the drug can be available from different manufacturers and with different units of measurement or package sizes. Matching NDC codes to HCPCS codes will require extensive manual effort by hospital staff. Once the hospital staff has assigned all NDCs to given HCPCS codes, they will have to calculate the average acquisition cost, which can differ for each individual NDC associated with a given HCPCS code. This process of obtaining the information in the format CMS requires will be extremely burdensome for hospital staff, which already are burdened by existing compliance and recordkeeping requirements.

Third, providers may purchase some drugs through distributors that are not their designated wholesaler. In these cases, the hospital would have to acquire individual invoices for purchases through these channels and then consolidate this information with the report from its wholesaler. Pulling individual invoices for drugs not purchased through the primary wholesaler would be cumbersome for hospitals.

These examples of the burden associated with producing acquisition data underscore the lack of research and preparation by CMS in creating the acquisition cost survey. To our knowledge, CMS has not worked with any stakeholders to gauge the true costs and burden involved in providing acquisition cost data. GAO, which was tasked with surveying hospitals for their acquisition costs in 2004 and 2005, highlighted the many obstacles to producing accurate acquisition cost data. It noted that surveying hospitals on acquisition cost data "created a considerable burden for hospitals as the data supplier and considerable costs for GAO as the data collector."[6] In its response to that report, HHS concurred with GAO, expressing reservations about surveying hospitals due to the burden placed on hospitals and their staff.

Concerns about burden are particularly pronounced for essential hospitals. There are significant administrative costs and compliance-related resources involved with 340B program participation, including the cost of hiring the appropriate staff, such as pharmacists and pharmacy technicians, to ensure compliance with the program's very technical and evolving requirements. In addition, 340B hospitals must invest in appropriate billing software and allocate resources to comply with the program and respond to audits. These costs are borne by the hospitals that already provide higher levels of uncompensated care compared with the average hospital, have margins significantly narrower than the average hospital, and treat a larger proportion of medically complex patients, such as those dually eligible for Medicare and Medicaid.

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[6] Government Accountability Office. Medicare Hospital Pharmaceuticals: Survey Shows Price Variation and Highlights Data Collection Lessons and Outpatient Rate-Setting Challenges for CMS. April 2006. https://www.gao.gov/assets/250/24e

CMS should not implement a proposal of this magnitude without fully considering the impact it will have on 340B hospitals and the complexities associated with producing acquisition cost data.

3. **CMS should not reimburse 340B hospitals less than the statutory default rate of 106 percent of ASP.**

CMS should reverse its unlawful payment cuts to 340B hospitals and revert to the statutory default payment rate of 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which the agency intends to continue for a third year in 2020, violate the Medicare statute. As we have urged in our previous comments, CMS should reverse these payment cuts and pay hospitals back at 106 percent of ASP plus interest.

The 340B program is critical to ensuring low-income and other disadvantaged people can access the types of services best provided by essential hospitals. Reductions in Medicare payment rates to 340B hospitals significantly erode the value of the program. These policies are most damaging to essential hospitals, given their high levels of uncompensated care, narrow margins, and large proportion of patients with Medicare and Medicaid coverage. Due to these cuts, hospitals have had to reconsider programs made possible by 340B savings. As a result of policies that significantly gut the program's benefit on top of these added expenses, some hospitals might have to pull back on the services they offer to patients.

CMS suggests that it could use 340B hospital acquisition cost data to determine Medicare reimbursement rates for Part B drugs. Any cuts, whether through a reduction in the ASP payment rate or by tying payment to acquisition cost, are devastating to 340B hospitals and their patients. Given the fragile financial position of essential hospitals, policy changes that jeopardize any piece of the patchwork support on which they rely, including the 340B program, can threaten their ability to maintain critical services. Therefore, we strongly advise CMS against reducing payments by tying them to acquisition costs.

Payment reductions to 340B hospitals have negative consequences for essential hospitals and their patients; therefore, **we urge the agency to revert to paying 340B hospitals at 106 percent of ASP.** Preserving the intent of the 340B program will better serve low-income Medicare beneficiaries and the Medicare program at large.

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO