



# AMERICA'S ESSENTIAL HOSPITALS

March 9, 2020

CMS Desk Officer  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17th Street NW  
Washington, DC 20503  
**Submitted via e-mail: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov)**

**Ref: CMS-10709 (OMB control number: 0938–New): Agency Information  
Collection Activities: Submission for OMB Review; Comment Request**

Dear CMS Desk Officer:

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 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—with additional reporting requirements on top of the existing, resource-intensive obligations they adhere to under the 340B program. Moreover, CMS' notice, which is being reviewed by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA), does not meet PRA requirements on accurate burden estimates, reliability and clarity of data produced by the information collection, and the utility of requested data.

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.<sup>1</sup> 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

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<sup>1</sup> 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/](http://www.essentialdata.info/). Accessed February 28, 2020.

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.<sup>2</sup> 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.”<sup>3</sup> 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 and unlawful 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 vulnerable and medically complex patients. CMS must immediately withdraw its unlawful Part B payment cut, make hospitals whole for the cuts that have taken place since 2018, and revert to the full 106 percent of ASP payment rate.

In previous comments to the agency on CMS' first notice on the proposed information collection request (ICR), America's Essential Hospitals expressed concern that CMS had not considered the administrative burden of the proposed ICR or its authority to collect this information in the proposed manner.<sup>4</sup> It is clear from the revised documentation provided by the agency that it still has not fully evaluated both its authority to conduct this survey and the true scope of the operational complexity associated with this request. Therefore, we urge CMS to withdraw its proposed ICR.

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<sup>2</sup> Ibid.

<sup>3</sup> H.R. Rep. No. 102-384, pt. 2 (1992).

<sup>4</sup> America's Essential Hospitals comment letter to William Parham III. November 27, 2019. <https://essentialhospitals.org/wp-content/uploads/2019/12/AEH-340B-acquisition-cost-survey-letter-11-27-19.pdf>.

**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's survey will be completed exclusively by 340B hospitals; hospitals not in the 340B program will not be required to report their acquisition costs. The selective collection of drug acquisition 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 that 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. CMS claims in supporting statement B that it does not need to conduct sampling because it is surveying 100 percent of the "respondent population." However, CMS is arbitrarily limiting the respondent population to one group of hospitals; surveying only this group of hospitals will not produce a reliable measure of average acquisition costs for SCODs across all hospitals.

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. 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 ICR.

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 and would require resources far exceeding the estimate provided by the agency. 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 PRA 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.”<sup>5</sup> 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.

As America's Essential Hospitals outlined in detail in its November 27 comments, CMS failed to consider the following aspects of the burden associated with the ICR:

- Hospitals do not readily have acquisition cost data available and will have to obtain it from a third party, such as their drug wholesaler. Wholesaler data are confidential and proprietary and these entities might require permission to release the data;
- Acquisition cost data downloaded from wholesalers is listed by national drug code (NDC) and will require significant manual matching and calculation to the Healthcare Common Procedure Coding System (HCPCS) code, which is the format CMS is requiring hospitals to report the data; and
- For certain drugs not acquired through the primary wholesaler, hospitals will have to request acquisition cost data from other distributors on a drug-by-drug basis.

Notwithstanding all these factors that America's Essential Hospitals and other commenters have raised, CMS has maintained the 48 hour per entity estimate from the first version of the notice issued last September. CMS has provided a few points of clarification, but these do not mitigate the burden on hospitals and their staff. For

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<sup>5</sup> Centers for Medicare & Medicaid Services. Supporting Statement—Part A. Hospital Survey for Specified Covered Outpatient Drugs (SCODs). CMS-10709; OMB 0938-New.

example, CMS provides a list of NDC to HCPCS crosswalks that hospitals can use to convert drug acquisition cost based on HCPCS units. However, hospitals will still have to get the data from a third party, crosswalk the codes, calculate acquisition costs at the HCPCS level, and verify the data and their calculations for accuracy prior to submission to CMS.

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.”<sup>6</sup> 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.

Under the PRA, the agency must certify that its information collections minimize burden on the individuals or entities responding to the ICR.<sup>7</sup> In the case of this ICR, it is clear that the agency has underestimated the associated burden and not taken sufficient steps to reduce the burden on providers. 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. **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’ proposed survey instrument lacks clarity and the agency has not ensured it will produce data of appropriate quality as required by the PRA.**

In the notice, CMS seeks comments on the quality, utility, and clarity of the data that will be collected through the survey. CMS has not taken appropriate steps to ensure the data produced by the survey will be of sufficient quality and clarity for the purposes of

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<sup>6</sup> 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/250/249967.pdf>.

<sup>7</sup> 44 U.S.C. § 3506.

**the PRA. CMS intends to use the information collected for Medicare payment purposes, so any data that is reported from the survey must be accurate and reliable.**

First, the data that CMS intends to collect are complex and voluminous. As we explain in the previous section, producing the data in the format CMS requires is not a quick or easy undertaking. However, CMS provides a mere 18 days—from March 23 through April 10—for hospitals to collect and report this data. Assuming that CMS' ICR is approved by OMB and published before then, hospitals will have to access the survey and train their staff on its implementation. If the hospitals can complete the survey in the short timeframe provided, CMS also must validate the data and ensure that reported data are consistent and accurate. Doing so will be a timely undertaking, and the agency has not indicated if it will have such a validation process in place.

Second, there is a significant likelihood for variation in the data reported by hospitals due to unclear instructions. For example, it is unclear how hospitals are to report data when there is variation in average drug acquisition costs across NDCs associated with a particular 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. Average costs per unit of a drug can vary based on the NDC code, so if multiple NDCs correlate to a given HCPCS code, it is unclear if hospitals are to list each average acquisition cost for each separate NDC or only list the drug once with acquisition cost at the HCPCS code level. CMS is requesting the average acquisition cost for an HCPCS code but provides hospitals the option of listing out each NDC associated with the HCPCS code. Because of this option, there will be variability in how hospitals report this information, as well as in the average costs reported by hospitals.

Finally, there is inconsistency across the notice, the proposed survey, and the supporting documentation about the group of hospitals responding to the survey. CMS states in the notice and supporting statement Part A that the number of respondents will be 1,338 hospitals. In supporting statement B, however, CMS states that the number of respondents will be 1,384 hospitals. Further, CMS revised supporting statement B to remove language limiting the survey to OPPS hospitals that participate in the 340B program. It appears from this change that CMS is intending for all 340B hospitals—and not just 340B hospitals paid under the OPPS—to complete the survey. If this is the case, the survey would include hospitals such as critical access hospitals, which are not paid under the OPPS. Yet, CMS' estimates of the number of respondents are inaccurate in that they do not account for non-OPPS 340B hospitals. The discrepancies in the estimated number of respondents, as well as the lack of clarity on which hospitals are meant to complete the survey, could result in either too many or too few hospitals responding to the survey. This would seriously undermine the clarity and utility of the data CMS collects. For these reasons, the ICR, as proposed by CMS, will not produce

clear, high-quality data that will be reliable for use in determining Part B drug reimbursement rates.

**4. CMS' proposed ICR is not necessary for the proper performance of the agency's functions, as the agency has an established statutory default payment rate of 106 percent of ASP at which it can reimburse hospitals.**

The collection of acquisition cost data for a subset of OPPS hospitals is not only unlawful but also unnecessary to the performance of CMS' functions. The PRA states that ICRs must have practical utility and be necessary for the proper performance of the agency's functions. CMS has an established, statutorily-set payment rate that it has used since 2013—payment at 106 percent of ASP. The U.S. District Court for the District of Columbia has unequivocally held that CMS' payment cuts, which use an alternative payment rate of 77.5 percent of ASP, violate the Medicare statute. **Therefore, CMS should reverse its unlawful payment cuts to 340B hospitals and revert to the statutory default payment rate of 106 percent of ASP.**

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 or make staffing cuts.

CMS suggests 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](mailto:eomalley@essentialhospitals.org).

Sincerely,

Bruce Siegel, MD, MPH  
President and CEO