



# AMERICA'S ESSENTIAL HOSPITALS

May 6, 2020

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Ave. SW  
Washington, DC 20201

**Ref: Hospital Survey for Specified Covered Outpatient Drugs Average Acquisition Cost (OMB control number 0938-1374)**

Dear Administrator Verma:

America's Essential Hospitals appreciates the actions of the Trump administration, including the Centers for Medicare & Medicaid Services (CMS), to mitigate the novel coronavirus (COVID-19) pandemic. CMS has provided critical flexibility to hospitals responding to the public health emergency through regulatory relief under its Section 1135 waiver authority. We commend the agency for these much-needed accommodations, which have allowed essential hospitals to direct their limited resources to COVID-19 response efforts. However, we are deeply troubled by CMS' ill-timed launch of the 340B Drug Pricing Program acquisition cost survey during the COVID-19 crisis. The decision to issue this survey undermines the progress CMS has made in extending regulatory relief to providers and will create a heavy burden on hospitals laboring to treat COVID-19 patients and recover from this pandemic. **With this in mind, we strongly urge the agency to immediately withdraw the 340B acquisition cost survey and to disregard any data that has been submitted during the survey window.**

America's Essential Hospitals is the leading champion for hospitals and health systems that care for large numbers of low-income patients—a commitment to mission that makes nearly all our members eligible to participate in the 340B program. They 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> These figures plainly demonstrate the challenges COVID-19 poses for essential hospitals and the bleak financial future they face in this costly public health battle.

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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. <https://essentialdata.info>. Accessed May 5, 2020.

This is an unprecedented and challenging time for our nation, as we face a public health emergency of unknown scope and duration. Essential hospitals, at the core of the nation's safety net, face this challenge with short supplies of available resources. Costs associated with COVID-19 continue to rise while revenues decrease. The complex and burdensome nature of the 340B survey, as well as the lack of notice and short timeframe to complete it, pose daunting challenges for covered entities, particularly as they struggle with limited resources during the COVID-19 pandemic.

In previous letters to the agency<sup>2</sup> and the Office of Management and Budget (OMB),<sup>3</sup> America's Essential Hospitals offered details on how the survey would burden hospitals by requiring staff to work with their drug wholesaler to extract 340B drug data, perform manual calculations, and conduct data matching to provide acquisition cost data in the format CMS requested. The survey will require hospitals to expend additional resources on dedicated personnel, staff training, and changes to hospital workflows. As we also noted in our previous letters, the survey is on tenuous legal grounds and is contrary to the Medicare statute's requirements on surveying a statistically valid sample of Outpatient Prospective Payment System (OPPS) hospitals. In its approval notice, OMB acknowledged these potential shortcomings and directed CMS to submit a report to OMB before using collected data in any rulemaking. In the report to OMB, CMS must clearly describe the scope and characteristics of the survey respondents and describe any "limitations in the generalizability of the information collected."<sup>4</sup>

Considering the burden associated with completing the survey, now is not the time for CMS to impose this data collection request on 340B hospitals. These hospitals are singularly focused on responding to the surge of COVID-19 patients and directing their staff toward these efforts. Even the Health Resources and Services Administration, the agency responsible for administering the 340B program, has relaxed select 340B program requirements, such as audits and other documentation requirements, to free up hospital resources during this public health emergency. Therefore, this burdensome data collection is contrary to efforts by both CMS and HRSA to ease the regulatory burden on hospitals at the front lines of the COVID-19 crisis.

Adding to the burden of completing the survey, CMS launched it the day after receiving OMB approval, providing no lead time and only three weeks for hospitals to complete the survey. Neither CMS nor Medicare Administrative Contractors actively shared the news of the survey's launch through existing channels, other than posting it on the OPPS website. Many hospitals had been unaware of the survey launch and others remain unclear about the instructions in the survey, especially given that CMS has changed the survey and survey instructions from proposed to final form.

Due to the survey's burdensome nature, its poor timing amid an unprecedented pandemic, and the lack of clear communication of its launch, **we urge CMS to withdraw the survey immediately. Furthermore, CMS should disregard any data it has collected and not use it in future rulemaking.** By taking these steps, CMS will lift an unnecessary burden from hospitals and improve their ability to manage their limited resources and valuable staff time to best protect the health of their communities during the COVID-19 pandemic.

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<sup>2</sup> America's Essential Hospitals Letter to Director William Parham III. November 27, 2019. Available at <https://essentialhospitals.org/wp-content/uploads/2019/12/AEH-340B-acquisition-cost-survey-letter-11-27-19.pdf>.

<sup>3</sup> America's Essential Hospitals Letter to CMS Desk Officer. March 9, 2020. Available at <https://essentialhospitals.org/wp-content/uploads/2020/03/AEH-340B-acquisition-cost-survey-letter-3-9-20.pdf>.

<sup>4</sup> Notice of Office of Management and Budget Action. OMB Control Number 0938-1374. April 23, 2020. Available at [https://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=202002-0938-001#](https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202002-0938-001#).

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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 & CEO