AMERICA'S ESSENTIAL HOSPITALS

May 11, 2023

Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
5600 Fishers Lane
Rockville, MD 20857

Re: Preserving Hospitals' Use of 340B Drugs for Patients at New Off-Site Clinics

Dear Administrator Johnson:

On behalf of our more than 300 member hospitals, which rely on the 340B Drug Pricing Program, America's Essential Hospitals is deeply concerned about reports the Health Resources and Services Administration (HRSA) will reverse its policy of allowing hospitals to use 340B discounted drugs for patients at offsite outpatient locations that have not yet appeared on a filed Medicare cost report.

Such a reversal, announced along with the end of other flexibility under the COVID-19 public health emergency (PHE), would significantly harm essential hospitals, which rely on HRSA guidance as they invest already scarce resources. Further, it would contradict our understanding of HRSA guidance on use of 340B discounts for eligible hospital patients. **We urge HRSA to clarify that hospitals may continue administering or dispensing 340B drugs to eligible patients in offsite outpatient locations of the hospital that will appear on the next filed Medicare cost report.**

If HRSA does intend to make such a significant reversal, we have serious concerns that the inadequate notice and lack of explanation for this change are unreasonable and inconsistent with requirements under federal administrative law. Given conflicting guidance as to the period for which HRSA's guidance would be applicable and the lack of a specific reference to this change in HRSA's public notice about the end of COVID-19 PHE flexibility, HRSA could not expect hospitals to comply by the end of the COVID-19 PHE. Essential hospitals cannot afford to replace millions of dollars in expected discounts, and patients cannot afford to go without the care those outpatient clinics would provide.

Essential Hospitals and the 340B Program

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals, most of which are 340B 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. They

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provide state-of-the-art, patient-centered care while operating on an average margin of 3.2 percent compared with 7.7 percent for other U.S. hospitals.[1]

A disproportionate number of our members' patients face sociodemographic challenges to accessing health care, including poverty, homelessness, language barriers, and low health literacy. Nearly 8 million people in essential hospital communities have limited access to healthy food, and 15.8 million live below the federal poverty line.[2] Members of America's Essential Hospitals have used 340B savings to create programs to tackle these financial and social challenges, as well as to improve health equity—showcasing how indispensable 340B savings are to hospitals operating on narrow margins.

In addition to a variety of primary care and specialty outpatient services on their main campuses, essential hospitals offer comprehensive, coordinated care across large ambulatory networks to bring vital services to where patients live and work. These ambulatory networks are a central part of essential hospitals' efforts to provide culturally competent care to patients who otherwise lack access to care. These networks allow essential hospitals to bring care closer to where their patients live, which is an important step in ensuring continuity of care for patients whose health is shaped by lack of transportation, unstable housing, and other social risk factors.

Our members provide comprehensive ambulatory care through networks of outpatient clinics that include onsite features—radiology, laboratory, and pharmacy services, for example—not typically offered by freestanding physician offices. Our members' ambulatory networks also offer behavioral health services, interpreters, and patient advocates who can access support programs for patients with complex medical and social needs.

HRSA's Guidance on Use of 340B Drugs in Unregistered Locations

America's Essential Hospitals applauded HRSA's June 2020 Frequently Asked Questions (FAQ) guidance on use of 340B discounted drugs in hospital offsite locations as a positive step that relieved unnecessary burden and expanded access to affordable medications for marginalized patients. HRSA did not go as far as we have advocated—it did not actually change its registration policy so that new outpatient sites can register as soon as they become integrated parts of the 340B-eligible hospital rather than months to a year later, when they appear on a Medicare cost report. But, in reiterating its unchanged registration requirements in response to a question posed during the pandemic, HRSA did make an important point in its response: that patients in those facilities "may still be 340B eligible to the extent that they are patients of the covered entity" as defined in the agency's 1996 patient definition guidance.

The 1996 guidance defines hospital patients based on (1) whether the hospital covered entity maintains a medical record for the individual; and (2) whether the individual receives care from a health care professional employed by or under contractual or other arrangements with the hospital covered entity, such that the hospital maintains responsibility for the care provided.

There is no question that once a location complies with Medicare's requirements for provider-based status, that location must be sufficiently clinically and financially integrated with the main hospital that patients at that location meet the definition of patients of the 340B-covered entity hospital. As a result, stakeholders across the 340B community understood that hospitals

[1] Clark D, Ramiah K, Taylor J, et al. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. www.essentialdata.info. Accessed May 10, 2023.
[2] Ibid.

could use 340B drugs for patients in locations of the hospital that had not yet appeared on a filed Medicare cost report. There was no indication in the text of the FAQ that the note related to patient definition was limited to the COVID-19 PHE, and when HRSA's compliance contractor published the FAQ on its "HRSA 340B FAQ Search" page without any reference to COVID-19 flexibility, that understanding was reinforced.[3]

Impact of a Reversal of HRSA's Position

A sudden reversal of HRSA's position, without adequate notice to 340B hospitals, would have profound impacts on essential hospitals and their disadvantaged patients.

One essential hospital invested $16 million into specialty clinics to give its underserved patients access to critical, life-saving services. Among these offsite clinics is an infectious disease clinic that treats vulnerable HIV and hepatitis C patients. These locations have operated under the main hospital's license and comply with Medicare's provider-based requirements. Under HRSA's June 2020 guidance, which was understood to be permanent, the clinics have been providing 340B drugs to their eligible patients. But if the June 2020 guidance were to be reversed, the hospital would have to wait until it files its 2023 Medicare cost report to register these clinics. This would delay the availability of 340B pricing to patients of the clinics until at least January 2024, resulting in an estimated $2.5 million impact per month and the loss of discounted drugs for these clinics' marginalized patients.

The same hospital also is in the process of building a new clinic set to be operational later this year, again assuming the ability to use 340B discounted drugs. If HRSA reverses its policy, this clinic could not prescribe or administer 340B drugs to its patients until January 2025—an 18-month delay in access to discounted drugs. Like other essential hospitals, this hospital is already in a financially precarious position, operating on a negative margin for 2023 and with only 30 days cash on hand. A reversal of HRSA's stated policy would be untenable for this hospital and would result in further financial losses and decreased 340B savings that it can reinvest into its community.

HRSA's clarification in the June 2020 guidance enabled the critical investments described above. **For the benefit of underserved communities and the stability of the 340B program, we urge swift communication from HRSA clarifying that hospitals may continue using 340B drugs for eligible patients in offsite outpatient locations of the hospital that will appear on the next filed Medicare cost report.**

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America's Essential Hospitals appreciates your expeditious consideration of 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

[3] See Apexus FAQ ID 4301. www.340bpvp.com/hrsa-faqs/340b-eligibility/registration. Accessed May 10, 2023.