American Hospital Association®

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June 5, 2023

Carole Johnson
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building
Room 13N188
Rockville, MD 20857

Re: 340B Hospitals' Access to 340B Pricing at New Outpatient Facilities

Dear Administrator Johnson:

On behalf of our approximately 2,000 340B member hospitals, the American Hospital Association (AHA) is writing to express our objection to the recent change to its prior policy by the Health Resources and Services Administration (HRSA) which allowed 340B hospitals to purchase 340B drugs for eligible patients at provider-based outpatient facilities that have not yet appeared on the hospital's most recently filed Medicare cost report. This sudden, unexplained change will have significant consequences for 340B hospitals. **We request that HRSA restore its prior policy and issue clarifying guidance as soon as possible that preserves 340B hospitals' ability to purchase 340B drugs at off-site clinics that have not yet appeared on hospitals' most recent Medicare cost report.**

On May 8, 2023, HRSA issued a notice instructing hospitals to stop purchasing 340B drugs at outpatient facilities that are yet to be included in the hospital's Medicare cost report and registered with HRSA. This notice came without warning, just three days before the end of the public health emergency (PHE). Hospitals were thus left with little time to comply.

While that timeframe alone is concerning, the agency's failure to adequately explain why it was making this abrupt about-face raises serious administrative law concerns.[*]

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[*] *E.g.*, *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016) ("[T] he unavoidable conclusion is that the 2011 regulation was issued without the reasoned explanation that was required in light of the Department's change in position and the significant reliance interests involved. In promulgating the 2011 regulation, the Department offered barely any explanation. A summary discussion may suffice in other circumstances, but here—in particular because of decades of industry reliance on the Department's prior policy—the explanation fell short of the agency's duty to explain why it deemed it necessary to overrule its previous position.").

HRSA did state that it was "returning to a pre-COVID policy regarding registration of outpatient policies." But it is not clear that HRSA's prior policy was tied to the pandemic or the PHE in any way.

To be sure, the issue of whether a hospital could register off-site outpatient facilities before being listed as a reimbursable line on its Medicare cost report was mentioned in the agency's COVID-19-related FAQs published in March 2020. But the discussion of this issue was ***not*** categorized as a COVID-19 PHE flexibility. While HRSA acknowledged that hospitals cannot register these outpatient facilities with the agency until they are included in the hospital's Medicare cost report, the FAQ noted that hospitals may be eligible to receive 340B drugs at such a facility for 340B-eligible patients of the hospital, citing HRSA's 1996 guidance on patient definition.[†]

The citation to HRSA's 1996 guidance was crucial. Given that reference, hospitals properly interpretated the FAQ to mean that if a patient meets the 340B patient definition set forth in the agency's 1996 guidelines, then the hospital can purchase 340B drugs for those patients at off-site outpatient facilities that had not yet appeared on the hospital's Medicare cost report. **Nowhere in the FAQ does it state that the 1996 guidance was no longer in effect or that the FAQ itself was a change in policy or that it was in any way tied to the PHE or a general flexibility afforded to hospitals during the pandemic.** In fact, the guidance appears only to provide further clarification that the 1996 guidance on 340B patient definition does not dictate the location of where the drug is dispensed so long as the patient receiving the drug is a 340B-eligible patient. Critically, HRSA's prime vendor also published this FAQ under their "340B Eligibility/Registration" page and did not indicate any relationship to the PHE. Instead, the prime vendor listed it as a stand-alone, permanent policy, consistent with the agency's 1996 guidance.

340B hospitals regularly rely on guidance and related FAQs published by HRSA and the 340B prime vendor to make important decisions about how to operationalize their 340B programs. This includes establishing new outpatient clinics as "ship to" locations for 340B drugs. **As a result, arbitrary and unexplained policy changes that go into effect with little to no time for hospitals to react create significant challenges, both operationally and financially**. The AHA has heard from several 340B member hospitals that the financial impact of this policy change could cost millions of dollars, as their access to 340B drugs for eligible patients could be delayed for several months while they wait for clinics to appear on their 2024 Medicare cost report. These financial losses are unsustainable for hospitals, especially given the current financial realities many of the nation's hospitals are facing from skyrocketing inflationary cost pressures to workforce and drug shortages.

[†] The 1996 guidance issued by HRSA sets out specific criteria for which patients 340B hospitals can use 340B drugs. Nowhere in the guidance does it limit at which locations 340B drugs can be used. (https://www.govinfo.gov/content/pkg/FR-1996-10-24/pdf/96-27344.pdf)

Therefore, we urge HRSA to promptly issue clarifying guidance that restores the prior policy consistent with the agency's 1996 340B patient definition guidance and ensures hospitals can purchase 340B drugs for eligible patients at outpatient facilities that are yet to be included on the hospital's most recently filed Medicare cost report.

We appreciate your consideration of this letter. We look forward to working with you on this issue and continuing our partnership to ensure a strong 340B program. If you have questions, please contact me or Bharath Krishnamurthy, director of health analytics and policy (bkrishnamurthy@aha.org) or Molly Collins Offner, director of policy (mcollins@aha.org).

Sincerely,

/s/

Melinda Hatton
General Counsel & Secretary
American Hospital Association

cc: Dr. Emeka Egwim, Director, Office of Pharmacy Affairs, HRSA