AMERICA'S ESSENTIAL HOSPITALS

April 30, 2020

Krista Pedley
Captain, U.S. Public Health Service
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane, Mail Stop 08W05A
Rockville, MD 20857

Ref: 340B Drug Pricing Program Flexibility During COVID-19 Emergency

Dear Captain Pedley,

America's Essential Hospitals appreciates the actions of the Trump administration to mitigate the COVID-19 pandemic and provide critical support to front-line responders as they confront this crisis. We are encouraged that the Health Resources and Services Administration (HRSA) has issued guidance on various aspects of the 340B Drug Pricing Program during this public health emergency. This guidance has helped clarify some lingering questions that covered entities have as they prepare for and respond to the COVID-19 pandemic. However, there are other program requirements HRSA can waive in response to the COVID-19 emergency to free up resources for essential hospitals as they see a surge of cases in their communities.

Our more than 300 member hospitals serve a disproportionate share of low-income patients; as such, most qualify to participate in the 340B program. Essential hospitals take extraordinary steps to respond to COVID-19, and many of these necessary efforts come with disruptions to daily operations and a significant price tag. They include constructing temporary spaces for diagnosing and treating COVID-19 patients; ensuring adequate stock of necessary equipment for patient care and personal protective equipment for front-line staff; and canceling planned surgical cases to increase capacity for COVID-19 cases.

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 center 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. Savings from the 340B program are more critical than ever to ensure our member hospitals can reach more patients and continue to offer vital services, safeguarding access to affordable health care for vulnerable individuals. While the 340B program is indispensable to our member hospitals and their patients, the complex and burdensome administration of the program poses significant challenges for covered entities, particularly as they struggle with limited resources during the COVID-19 pandemic.

We understand HRSA has issued some guidance to date that is specific to COVID-19, but this guidance has been not always been clearly communicated to all covered entities. Instead, it has been released in an incremental manner without clear notification to covered entities about the release of new updates. In many cases, HRSA has noted it is providing flexibility on a case-by-

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case basis for covered entities who reach out to the agency with the need for specific accommodations. Although we appreciate this flexibility, this piecemeal approach leaves other covered entities out of the loop and puts the burden on covered entities to affirmatively request flexibility from HRSA.

Instead of extending flexibility on a case-by-case basis, there are certain program requirements for which HRSA can issue clear guidance allowing all covered entities to direct their limited resources to their COVID-19 response efforts. HRSA can take the following steps to mitigate uncertainty among covered entities and reduce burdensome program requirements during the COVID-19 pandemic.

1. HRSA should allow newly eligible covered entities and sites to immediately register and begin purchasing 340B drugs for the pendency of the public health emergency declaration.

HRSA should allow covered entities and child sites that can demonstrate they are eligible for the 340B program to immediately register and begin purchasing lifesaving drugs at discounted prices. The annual registration process for covered entities has become increasingly burdensome and unpredictable. Covered entities must wait for the first 15 days of a calendar quarter to register to participate in the program and then must wait until the next quarter to begin purchasing 340B drugs. Moreover, if a covered entity already in the program wants to register a new clinic as a child site, it must ensure that the clinic appears as a reimbursable facility on a *filed* hospital cost report before it can register this clinic. This has created a needless administrative barrier to adding outpatient facilities to the 340B program. Because cost reports are retroactive, gaps exist between the point at which a new facility begins operations and the end of a hospital fiscal year; the end of a hospital fiscal year and the due date for a filed cost report (up to five months); and the quarterly deadlines to enroll in the 340B program. As such, a covered entity could be forced to wait longer than a year to receive discounts on drugs dispensed to covered entity patients seen at a new outpatient facility. Especially as hospitals respond to the COVID-19 pandemic by expanding access to patients through outpatient clinics, it is critical that they be immediately able to register these new sites and realize savings on covered outpatient drugs.

HRSA has posted an announcement on its website that some covered entities, "upon request and review," can immediately enroll in the 340B program. HRSA should clarify that this policy applies not just to newly eligible covered entities but to child sites, as well. Additionally, HRSA can clarify it will waive the filed cost report requirement, allowing a child site to register immediately. Not only will this allow the covered entity to immediately purchase 340B drugs at these locations, but it also will be consistent with past HRSA guidance allowing outpatient facilities to receive 340B discounts as long as they are "a reimbursable facility included on the hospital's Medicare cost report."[1]

2. HRSA should relieve administrative burden during the COVID-19 pandemic by suspending program audits.

HRSA should suspend covered entity audits during the COVID-19 emergency. America's Essential Hospitals supports an audit process that appropriately ensures compliance with 340B program requirements. Covered entities—particularly hospitals—are audited exponentially more frequently than manufacturers and are expected to maintain rigorous self-auditing, and even independent audits, that contribute to a meaningful burden of ensuring compliance. Audit findings can have serious consequences for covered entities, including sanctions and termination

[1] 59 Fed. Reg. 47,884, 47,886 (September 19, 1994).

from the 340B program. Essential hospitals also face steep penalties for noncompliance and receive audit findings even for minor Office of Pharmacy Affairs Information System (OPAIS) errors. Hospitals have rigorous internal recordkeeping and internal audit procedures to ensure compliance with complex program requirements. Responding to detailed audit requests is a significant time and resource investment for essential hospitals that they cannot afford as they respond to COVID-19. **HRSA has said that it will conduct audits virtually during the emergency declaration, but we urge the agency to go one step further and suspend audits altogether until the emergency declaration expires.**

3. HRSA should disregard DSH adjustment percentage changes during the COVID-19 emergency declaration.

Hospitals respond to the pandemic by delaying non-emergent procedures so that they can prioritize COVID-19 and other high-risk cases. The pandemic has severely disrupted daily hospital operations, including changing the types of patients and cases hospitals see day-to-day. These changes likely will alter payer mix, changing a hospital's disproportionate share hospital (DSH) adjustment percentage.

Depending on the classification of the hospital (e.g., DSH, sole community hospital, rural referral center), 340B hospitals are required to satisfy a minimum DSH percentage. Under current program rules, if a hospital drops below the required threshold, it must notify HRSA and will no longer be eligible for the 340B program. For a hospital with a DSH adjustment percentage hovering around the eligibility threshold, it is possible to fall below the threshold temporarily due to changing payer mix. **To ease this unintended consequence of treating COVID-19 patients, HRSA should disregard any changes in DSH adjustment that arise as a result of a hospital's response to the COVID-19 crisis.** This will allow hospitals to shift their attention to the most serious COVID-19 and other emergent cases without being concerned about how these changes will affect their 340B eligibility.

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America's Essential Hospitals appreciates your consideration of this comment letter. If you have any questions, please contact Erin O'Malley, senior director of policy, at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

Bruce Siegel, MD, MPH
President and CEO