



**American Hospital
Association®**

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April 21, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

On behalf of our nearly 2,000 340B member hospitals, the American Hospital Association (AHA) urges the Department of Health and Human Services (HHS) and the Health Resources and Services Administration (HRSA) to provide flexibility in the administration of the 340B Drug Pricing Program to better enable these hospitals to serve their communities during the COVID-19 national emergency. Specifically, we urge you to waive: 1) the group purchasing organization (GPO) prohibition applied to certain 340B hospitals, which may challenge their ability to get needed drug therapies during the emergency, and 2) eligibility rules that may disqualify current 340B hospitals. These waivers will help provide hospitals on the frontline of the COVID-19 fight with the resources needed to fulfill their missions of caring for their communities.

Hospitals are in need of critical drug therapies to care for patients with COVID-19. Certain 340B hospitals, such as those that qualify through their Medicare disproportionate share hospital (DSH) adjustment percentage, children's hospitals, and free-standing cancer hospitals, are prohibited from purchasing outpatient drugs through a GPO. On March 22, HRSA released guidance to 340B hospitals that stated that a 340B hospital subject to the GPO prohibition and facing a drug shortage during the COVID-19 pandemic could purchase drugs through a GPO without seeking HRSA approval. While this guidance is helpful, we urge HHS/HRSA to waive the GPO prohibition altogether during this time period. The COVID-19 national health emergency has exposed significant weaknesses in the pharmaceutical supply chain. Waiving the GPO prohibition would allow all 340B hospitals more timely access to critical outpatient drugs. In addition, with the prohibition waived, these hospitals could purchase certain drugs at a lower price, which is desperately needed as hospital expenses have increased significantly to build new infrastructure and surge their workforce to meet the demands created by COVID-19 while simultaneously losing revenue from canceled non-emergency procedures.

We also ask that you waive certain eligibility requirements to ensure that these hospitals on the frontline are not inadvertently penalized for a temporary change in patient mix. 340B hospital eligibility is primarily determined by a formula intended to measure a

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hospital's low-income patient mix (the Medicare DSH adjustment percentage). Many of our 340B hospital members have raised concerns that they may be at risk of losing their 340B eligibility because of a change in patient mix as they meet the challenge of treating COVID-19 patients.

Patient mix could change because of an influx of admissions of non-Medicaid or non-Medicare beneficiaries or from a general decrease in inpatient care as services are either delayed or, when appropriate, transitioned to the outpatient setting to increase inpatient capacity for a COVID-19 surge. Changes to patient mix as a result of these factors could impact a hospital's future 340B eligibility. 340B hospitals should not be penalized for ensuring they are ready and able to serve their community during this health crisis. We urge HHS/HRSA to waive temporarily the 340B Medicare DSH threshold during redetermination for current 340B hospitals. By doing so, a hospital's status would not be at risk due to these time-limited changes in their patient mix and would help ensure that these hospitals will be able to continue to rely on the 340B program to stretch scarce resources to provide care to vulnerable communities.

Finally, we encourage HHS/HRSA to suspend 340B hospital audits during the COVID-19 emergency. 340B hospitals in the throes of this health crisis need every able staff resource to enable them to meet and manage new demands.

We appreciate your leadership and the ongoing work of the White House Coronavirus Task Force. We look forward to continuing to work with you during this critical time to protect the health of our nation.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President