American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

March 2, 2022

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Becerra:

On behalf of our nearly 2,000 340B member hospitals, the American Hospital Association (AHA) is again writing to urge that the Department of Health and Human Services (HHS) ensure hospitals participating in the 340B Drug Pricing Program do not lose access to the program as a result of changes in patterns of patient care due to the COVID-19 public health emergency (PHE).

The COVID-19 pandemic has ravaged the United States, with nearly 80 million people infected and over 920,000 people dead through mid-February 2022. Our nation's hospitals and health systems have been on the front lines of this devastating virus and have collectively cared for nearly 4.5 million patients hospitalized with COVID-19. Like many hospitals throughout the country, a number of 340B hospitals have endured immense financial and operational challenges, including mandatory shutdowns of non-emergent procedures to make way for increased demand for COVID-19 care. For some 340B hospitals, these challenges have led to changes in their payer mix during the PHE that put their access to the 340B program at risk.

Losing access to 340B discounted drugs and program savings could jeopardize the ability of these hospitals to provide critical services for the patients and communities they serve, which would be particularly catastrophic at a time when they remain on the front lines of the ongoing pandemic. **To remedy this issue, we specifically request a waiver of the Medicare-based eligibility criterion for 340B hospitals enrolled in the program during the PHE that experienced a temporary change in patterns of patient care due to the COVID-19 pandemic.**

In order to qualify for the 340B program, hospitals must meet several rigorous criteria. One of the primary 340B eligibility criteria is the Medicare disproportionate share hospital (DSH) adjustment percentage, which is based on a hospital's volume of inpatient Medicaid and Medicare Supplemental Security Income (SSI) patients as reported by the hospital on its most recently filed Medicare cost report. As a result of

these changes in hospitals' payer mix, some 340B hospitals filing their Medicare cost reports that reflect their patient services during the PHE period will be at risk of losing their 340B eligibility. This loss of access to the 340B program is an unfortunate consequence of COVID-19-related-changes in payer mix. The COVID-19 PHE resulted in many hospitals suspending non-urgent services and shifting resources to enable greater capacity to treat COVID-19 patients. These actions combined with a slow resurgence of patient volumes have changed some hospitals' payer mix – particularly lowering the proportion of hospital patients who are Medicaid or Medicare SSI patients.

As patients have delayed care due to the pandemic, many hospitals are now seeing patients with higher acuity, requiring longer hospital stays and more intensive treatment. In fact, the latest data released by Kaufman Hall in their monthly National Hospital Flash Report show that patient length-of-stay has increased 9.9% year-to-date compared to pre-pandemic levels, which has contributed to a 2.5% and 2% year-to-date increase in patient days and adjusted patient days, respectively, compared to pre-pandemic levels.[1] At the same time, some hospitals are seeing a decrease in the number of Medicaid patients they are treating, resulting in a precipitous drop in their Medicaid ratio. For some hospitals this drop in the Medicaid ratio has not been offset by any increase in the Medicare SSI ratio as the Centers for Medicare & Medicaid Services (CMS) delayed its updates to these ratios. As a result, for some hospitals the decrease in their Medicaid ratio has driven a decrease in their Disproportionate Patient Percentage (DPP) and thereby has decreased their DSH adjustment percentage. Without a waiver, these hospitals will be forced out of the 340B program, losing access to discounted drugs and program savings used to help provide care to the vulnerable communities they serve, many of which have been disproportionately affected by the COVID-19 pandemic.

Under section 1135 of the Social Security Act, the HHS Secretary may temporarily waive or modify certain Medicare, Medicaid and Children's Health Insurance Program (CHIP) requirements. The waiver of these requirements is to ensure that:

- sufficient health care items and services are available to meet the needs of individuals enrolled in these federal programs in the emergency area and time periods; and
- providers who treat such individuals in good faith can be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).

HHS has already used section 1135 authority to create significant and critical regulatory flexibilities to help health care providers address COVID-19. Two of these waivers grant eligibility flexibility for Sole Community Hospitals (SCH) and Medicare Dependent Hospitals (MDH).[2] Specifically they include a waiver of distance, market share, and bed requirements for SCHs, and inpatient days or discharge criteria for MDHs. The rationale for both of these eligibility waivers was to allow hospitals to meet the needs of the communities they serve during the PHE while also providing increased capacity for

[1] https://www.kaufmanhall.com/insights/research-report/national-hospital-flash-report-january-2022
[2] https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf.

treating COVID-19 patients. This same flexibility should be applied to 340B hospitals that have faced and continue to face similar challenges.

One such solution would be to waive the DSH eligibility criteria for hospitals that participated in the 340B program during the PHE. This action would be in line with similar waiver authority exercised under the SCH and MDH 1135 waivers. For a given 340B hospital, the Medicare DPP calculation required by Section 1886(d) (5) (F) of the Social Security Act and 42 CFR 412.106 could be set at the hospital's DPP prior to the PHE to ensure their continued eligibility for the program. This waiver of the DSH eligibility requirement would apply for any cost reports filed covering time periods during the PHE and would only apply to 340B hospitals that were enrolled in the 340B program during the PHE. By limiting the waiver to hospitals already participating in the program during the PHE, this action would not enable otherwise ineligible hospitals to newly qualify for the program.

Since our prior letter to you on this very issue, some of our member 340B hospitals have reported that they have either already lost their 340B eligibility or fear that they will lose their eligibility when their next Medicare cost reports are due to be filed. Absent the COVID-19 pandemic, these hospitals would have continued to be eligible for the 340B program. As such, these hospitals and their patients should not be penalized by losing access to the 340B program as a result of the COVID-19 pandemic, especially at a time when a program like 340B is critical to maintaining patient care. As we detail above, we believe not only that HHS has the requisite authority to exercise such a waiver in this case but also that not exercising such a waiver would seriously jeopardize the ability of some 340B hospitals to continue to provide critical services and programs for the vulnerable patients and communities they serve.

Therefore, we urge HHS to use its 1135 waiver authority to temporarily waive the 340B Medicare DSH percentage eligibility criteria and allow 340B hospitals that have participated in the program during the PHE to have continued access to the 340B program.

We appreciate your commitment to the 340B program and look forward to working with you during this critical time to ensure hospitals can continue caring for their communities. Please contact me if you have questions, or feel free to have a member of your team contact Robyn Bash, vice president of government relations and public policy operations, at rbash@aha.org.

Sincerely,

/s/

Richard J. Pollack
President and Chief Executive Officer