

March 31, 2021

The Honorable Xavier Becerra
Secretary, U.S. Department of Health & 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) urges the Department of Health and Human Services (HHS) to ensure hospitals currently participating in the 340B Drug Pricing Program continue to have access to the program despite changes in their payer mix as a result of the COVID-19 public health emergency (PHE).

Like many hospitals throughout the country, a number of 340B hospitals have endured immense financial and operational challenges that have altered their payer mix during the PHE, and as a result are now facing the possible loss of access to the 340B program. Losing access to 340B discounted drugs and program savings could jeopardize the ability of these hospitals to provide critical services for their communities, which would be particularly catastrophic at a time when they remain on the front lines of the ongoing pandemic. **We specifically request a waiver of certain 340B program eligibility criteria for 340B hospitals enrolled during the PHE that may have experienced a temporary change in payer mix due to the COVID-19 pandemic.**

This potential loss of access to the 340B program is an unfortunate consequence of COVID-19-related changes in payer mix over the past year. The COVID-19 PHE resulted in 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 hospitals' payer mix – particularly lowering the proportion of hospital patients who are Medicaid or Medicare SSI patients. One of the primary eligibility criteria for hospitals in the 340B program – the Medicare disproportionate share hospital (DSH) patient percentage (DPP) adjustment – is based on a hospital's volume of inpatient Medicaid and Medicare 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 2020 patient services will be at risk of losing their 340B eligibility. 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.

HHS has already taken significant action in exercising these regulatory flexibilities to help health care providers address COVID-19 by enacting a series of waivers using the 1135 authority (retroactive to March 1, 2020 through the end of the PHE). Two of these waivers grant eligibility flexibility for Sole Community Hospitals (SCH) and Medicare Dependent Hospitals (MDH).¹ 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 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 DPP eligibility criteria for hospitals currently participating in the 340B program, which has been distorted by the COVID-19 pandemic.

We urge HHS to use the 1135 waiver authority to temporarily waive the 340B Medicare DSH DPP eligibility criteria and allow currently participating 340B hospitals continued access to the program. 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 Social Security Act Section 1886(d) (5) (F) and established at 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 DPP eligibility requirement could apply for any cost reports filed covering time periods during the PHE and only apply to 340B hospitals that are enrolled in the 340B program during the PHE.

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, at rbash@aha.org.

Sincerely,

/s/

Thomas P. Nickels
Executive Vice President

¹ <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>.