American Hospital Association™
Advancing Health in America

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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 5,000 member hospitals, health systems and other health care organizations, our clinician partners — including more than 270,000 affiliated physicians, 2 million nurses and other caregivers — and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) respectfully requests the opportunity to meet with you to discuss how best to ensure prompt repayment of 340B hospitals following the Supreme Court's decision in *American Hospital Association v. Becerra*, without penalizing the rest of the hospital field.

Last week, the Supreme Court unanimously held that the prior Administration acted unlawfully when it severely reduced Medicare reimbursement rates for outpatient drugs provided by hospitals participating in the 340B program. In reaching that conclusion, the Court correctly recognized that hospitals eligible for 340B drug discounts "perform valuable services for low-income and rural communities but have to rely on limited federal funding for support," and that the decision to cut reimbursement rates had "immense economic consequences." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13, 2). Given the vital role that 340B hospitals play in serving vulnerable communities, they should be repaid the funds that have been withheld from them without delay. They also should be paid for *all* of the years (2018-2022) in which the Centers for Medicare & Medicaid Services (CMS) illegally cut reimbursement rates.

We are concerned, however, that despite the Supreme Court's conclusive decision, resolution of these issues could be bogged down in needless litigation, and that hospitals will not be appropriately compensated at a time when they are weathering significant financial challenges on many fronts. For example, after a federal district court initially held that the cuts were unlawful, the prior Administration took a series of actions that would have delayed relief, including (1) requesting a remand to the Department of Health and Human Services (HHS) to determine the appropriate remedy, (2) conducting

notice-and-comment rulemaking on that remedy, (3) opposing the AHA's motion for an expedited remedy or for a firm date by which the agency should propose a remedy and (4) suggesting that affected hospitals must pursue repayment on a hospital-by-hospital basis. These actions would have prevented hospitals from receiving prompt repayment of funds that, as the Supreme Court noted, have "helped keep 340B hospitals afloat." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13).

Furthermore, the prior Administration mistakenly took the position that HHS is required to maintain budget neutrality when determining the appropriate remedy. As you know, that position would mean that some hospitals will be forced to pay back money spent years ago — including during the COVID-19 pandemic — because *the federal government* made a legal error. Hospitals should not have to pay for the agency's mistakes. Instead, this Administration should take the sensible (and legally correct) position that budget neutrality is not required when a court — here, all nine Justices of the Supreme Court — concludes the agency violated the law.[1]

Finally, HHS unlawfully cited on a 2020 survey when proposing even deeper reimbursement cuts for certain years. This survey was fatally flawed in two critical respects. *First*, it was issued during the onset of the COVID-19 public health emergency, precisely when 340B hospitals were struggling to marshal critical resources to respond to the pandemic. Unsurprisingly, only 7% of hospitals that received the survey responded with the actual acquisition cost data. That response rate fails to meet the statutory requirement that a survey must "…have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." 42 U.S.C. § 1395l(t)(14)(D)(iii). *Second*, the survey did not meet the statutory requirements when it specified that only 340B hospitals were required to complete the survey. Given these fundamental flaws in the design and conduct of the 2020 survey, we expect that HHS will not rely on its results to support any future reimbursement cuts. As the Supreme Court noted in its decision, the statute "reflects a careful congressional focus not only on the goal of proper reimbursement rates, but also on the appropriate means to that end." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ____ (2022) (slip op., at 9). Reliance on the 2020 survey would be an improper means to an improper end.

[1] In briefing before the district court, the AHA and its *amicus* offered several additional reasons why the agency is not required to force non-340B hospitals to repay funds it received as a result of the agency's own legal errors. *See, e.g.*, Plaintiffs' Response Brief on Remedies, *Am. Hosp. Ass'n v. Becerra*, Case No. 1:18-cv-2084-RC, Dkt. 37 (Feb. 14, 2019). For example, the budget neutrality provision on which the prior Administration relied addresses the *prospective* payment system and thus focuses on "estimated" amounts for the coming year. *See* 42 U.S.C. § 1395l(t)(9)(B). But there is nothing prospective about the current situation; 340B hospitals must be repaid for *historic* underpayments based on the agency's erroneous legal interpretation. In making this and other arguments, these briefs clearly establish that the prior Administration erred in claim that budget neutrality is required, just like it erred in its claim that it had the legal authority to impose the reimbursement cuts in the first place.

The unanimous Supreme Court decision made it unmistakably clear that the prior Administration took unsound legal and policy positions, and we hope that you will work us to ensure that hospitals and health systems receive the funding to which they are entitled. Doing so will help hospitals provide vital "'health care to the uninsured, underinsured, and those who live far from hospitals and clinics.'" *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ____ (2022) (slip op., at 13). **We respectfully request the opportunity to meet with you to resolve these issues in an expeditious manner. We are confident that we can work together to assure a fair and equitable resolution of these issues, which have already taken far too long to resolve, at great cost to the entire hospital field.**

We will contact your office to schedule a meeting. If you have questions or concerns in the meantime, please contact me or feel free to have members of your team contact our General Counsel, Mindy Hatton, at **mhatton@aha.org** or 202-329-5955, or our Deputy General Counsel, Chad Golder, at **cgolder@aha.org** or 202-646-4624.

Sincerely,

Richard J. Pollack
President and Chief Executive Officer

cc:
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services
Samuel R. Bagenstos, General Counsel, Department of Health and Human Services