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

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Samuel Bagenstos
General Counsel
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Mr. Bagenstos:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical 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 now that the district court in *American Hospital Association v. Becerra* has remanded the question of how to repay 340B hospitals to the Department of Health and Human Services (HHS).

For five years, HHS has unlawfully withheld funds from 340B hospitals resulting from its cuts to reimbursement rates for outpatient drugs purchased under the 340B program. Last June, shortly after the Supreme Court held these cuts to be unlawful, AHA President and CEO Richard J. Pollack wrote to HHS Secretary Xavier Becerra asking that HHS promptly repay 340B hospitals without seeking to claw back funds from the rest of the hospital field. He explained that 340B hospitals, like other hospitals in the field, are "weathering significant financial challenges," and that these funds, as the Supreme Court observed, "help[] keep 340B hospitals afloat," *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13).

Regrettably, more than six months later there has been little progress in repaying 340B hospitals what they are owed. Just as the AHA feared in our June letter, this issue quickly became "bogged down in needless litigation." For example, rather than agreeing to halt its unlawful policy for the remainder of 2022, the agency had to be forced by court order to pay 340B hospitals at the lawful rate. *See Am. Hosp. Ass'n v. Becerra*, 2022 WL 4534617, at *4 (D.D.C. Sept. 28, 2022) ("HHS should not be allowed to continue its unlawful 340B reimbursements for the remainder of the year just because it promises to fix the problem later."). And rather than affirmatively proposing a mechanism for repaying hospitals, HHS repeatedly argued for a remand to the Department — the result of which will be *more than a year* of delay between the Supreme Court's decision and any expected

repayment. While the AHA appreciates that HHS recently suggested in its Unified Plan that it will propose a remedy by April 2023 and represented to the district court that it "intends" to finalize that remedy "before the 2024 OPPS rulemaking cycle is complete," even this timeframe unnecessarily deprives 340B hospitals of funding at a time when they desperately need it to best serve their vulnerable patients and communities.

I write in hope of expediting this administrative process and avoiding further legal challenges. Now that the case has been formally remanded and HHS is presumably drafting its notice of proposed rulemaking, the AHA respectfully requests the opportunity to meet with the responsible HHS team to discuss its forthcoming remedial proposal.

As the AHA has stated before, we are willing to work with HHS 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. In the meantime, please consider the principles outlined below in the spirit with which they are offered: A sincere attempt to accelerate the regulatory process so that 340B hospitals promptly receive the funding they need to continue to "perform valuable services for low-income and rural communities." *Am. Hosp. Ass'n v. Becerra*, 596 U.S. ___ (2022) (slip op., at 13).

***First*, HHS must repay each 340B hospital the full amount that was unlawfully withheld between January 2018 and September 2022**. More than 1,000 340B hospitals located across the country serving both urban and rural underserved populations suffered reimbursement cuts resulting from HHS' unlawful policy. Each hospital is entitled to complete repayment. Determining how much money is owed to each hospital is not difficult, and HHS can efficiently conduct that analysis using its National Claims History database. HHS can easily isolate claims submitted by a particular hospital using the "JG modifier," which HHS uses to identify claims for 340B drugs that were paid at the reduced rate under the calendar years' 2018-2022 hospital outpatient prospective payment system rules. Once HHS calculates the total amount that each hospital was paid for all 340B claims across all five years of the unlawful policy, that amount can be multiplied by a single numerical factor (1.3678, or 1.06/0.775), which will be uniform across hospitals. This straightforward calculation will yield exactly how much HHS should have paid each hospital and thus how much its reimbursement was unlawfully reduced. Each hospital can then be compensated according to the amount that its reimbursements were reduced (plus interest, as explained below). We have been reliably informed by former Centers for Medicare & Medicaid Services (CMS) officials that the agency can complete this process quickly and with minimal administrative effort.

***Second*, HHS must repay each 340B hospital promptly**. HHS has had several years and multiple comment periods to develop this simple approach, which the AHA first identified in January 2019 during briefing before the district court. *See* Plaintiffs' Supplemental Brief on Remedies at 2-4 (Dkt. 32), *Am. Hosp. Ass'n v. Becerra*, No. 1:18-cv-2084; *see also* Letter from Thomas P. Nickels, AHA Executive Vice President to Seema Verma, Administrator, Centers for Medicare & Medicaid Services, Re: CMS–

1717–P Proposed Rule (Vol. 84, No. 154) at 34-36 (Sept. 27, 2019). Accordingly, HHS should make a one-time payment to all affected 340B hospitals after completing the calculations described above.

To the extent, however, that HHS is concerned about the total size of the underpayments, it bears reminding that this a function of HHS' own decisions to implement an unlawful policy for so long. It is not a legitimate justification for further delay. But if the agency disagrees and seeks to stretch repayments to each hospital over a number of years, it also must bear in mind that it is required to pay interest on all unreimbursed funds (see below). If HHS is prepared to pay interest, the AHA would be open to discussing a two or three-year repayment period.

***Third*, HHS may not impose a prospective remedy.** At various times during the litigation, HHS suggested that it might impose a prospective remedy, as it did in response to the "2-midnights rule" litigation (*Shands Jacksonville Med. Ctr., Inc.*), whereby the agency would adjust reimbursement rates in 2024 to make up for the shortfalls between 2018 and 2022. In this case, a prospective solution would be arbitrary and capricious.

As an initial matter, there is no guarantee that all 340B hospitals that suffered illegal cuts between 2018 and 2022 would receive upward adjustments in 2024 (or any future year). Registration for the 340B program is conducted on a quarterly basis, which means that hospitals enter and exit the program with some regularity. For example, approximately 100 hospitals that were subject to the payment cuts in 2018 are not currently participants in the 340B program. A prospective remedy therefore is no guarantee that any individual hospital will be repaid the money it is owed. The Department confronted this issue in *Shands* and created a separate process for the "very small number" of hospitals that could not be paid because they closed or were converted. (*See* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2017 Rates, 81 Fed. Reg. 56,762, 57,060 (Aug. 22, 2016); *see also Shands Jacksonville Med. Ctr., Inc. v. Azar,* 366 F.Supp.3d 32, 53 (D.D.C. 2018)). To create a separate process here, however, is unnecessary given the simple alternative described above. What's more, it is difficult to imagine that a separate process for these hospitals would look anything different from AHA's proposal, which begs the question why that process wouldn't be used for all 340B hospitals in the first place?

More generally, when the D.C. Circuit upheld the *Shands* remedy, it observed that a prospective approach was "the most transparent, expedient, and administratively feasible method" to address the past effects of the rate reduction" at issue. (*Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1120 (D.C. Cir. 2020) (internal quotation marks omitted)). Here, by contrast, the simplest, fastest, and most administratively feasible approach is the one AHA has proposed: A lump-sum repayment based on a straightforward calculation of what each hospital is owed. This approach requires minimal Department effort to determine, simple math, and swift repayment of funds as soon as HHS completes the arithmetic. Put another way, this approach satisfies *all* of the

Department's potential interests: "finality, "administrative efficiency," and "increased accuracy." (*Methodist Hosp. of Sacramento v. Shalala*, 38 F.3d 1225, 1235 (D.C. Cir. 1994), *cited in Shands Jacksonville Med. Ctr., Inc*., 959 F.3d at 1119-1120).

***Fourth*, HHS is required to pay hospitals interest on its underpayments until they are fully repaid**. HHS' continued delay in repaying 340B hospitals carries financial consequences. HHS has determined that, in light of the Supreme Court's decision, 340B hospitals were underpaid between 2020 through 2022, which is the same determination that the Supreme Court itself made for 2018 and 2019. (*See* Defendants' Opposition To Plaintiffs' Motion To Hold Unlawful And Remedy Defendants' Past Underpayment Of 340B Drugs at 6 (Dkt. 76), *Am. Hosp. Ass'n v. Becerra*, No. 1:18-cv-2084 ("Defendants agree with Plaintiffs that the Supreme Court's decision in this case for the 2018 and 2019 calendar years effectively resolves Plaintiffs' claims relating to the 2020, 2021, and 2022 calendar years. Defendants therefore do not oppose Plaintiffs' motion to the extent it seeks a declaration that the 2020, 2021, and 2022 OPPS Rules are unlawful insofar as they vary the reimbursement rate for 340B hospitals from ASP plus six percent absent a survey of hospitals' acquisition costs.")). HHS also has determined the amount of the underpayment: The difference between what 340B hospitals were paid and average sales price plus 6%. Consequently, federal law requires the government to pay interest on all underpayments from 2018 to 2022 until those underpayments are fully remedied. (*See* 42 U.S.C. § 1395*l*(j)). It is worth noting that the current interest rate, which is updated quarterly, is 11.25%. (*See* Notice of New Interest Rate for Medicare Overpayments and Underpayments–2nd Qtr Notification for FY 2023 at https://www.cms.gov/files/document/r11784fmpdf.pdf).

***Fifth*, HHS has no legal authority to recoup funds from the hospital field to achieve budget neutrality**. The AHA has previously explained why HHS may not, as a matter of law, seek to recoup funds from the remainder of the hospital field to pay for the agency's own mistakes. Our district court briefing and comment letters explain in great detail why, under the relevant statutes, budget neutrality can be used only to set *future* payments for Medicare items and services because it is tied to "the estimated amount of expenditures" for an upcoming year (42 U.S.C. § 1395l(t)(9)(B)). Indeed, the plain text of the OPPS statute says *nothing* about past years or retrospective clawbacks; it only addresses future estimates and forward-looking periodic reviews.

To this day, HHS has *never* identified a textual basis for its asserted authority to claw back years of funding that hospitals have long since spent. Nor has HHS identified a single historical example when it has attempted to do so. And it has never grappled with the fact that HHS previously exempted certain 340B hospitals from its reimbursement cuts (*e.g*., rural sole community hospitals and free-standing children's and cancer hospitals), but those hospitals would be forced to return funds if the Department pursued recoupment to achieve budget neutrality. Instead, HHS has relied exclusively on a stray passage from the D.C. Circuit's decision in *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004), but that discussion was manifestly *dicta* and, in any event, would not bind a different court of appeals faced with a legal challenge to any clawback remedy. At the

very least, the proposed rule must address these textual, historical, practical and precedential shortcomings. Because there are no satisfactory responses, however, the proposed rule should announce — once and for all — that the agency *will not* seek to recoup funds that hospitals have long since spent. Anything else would be unlawful, unwise policy, and would generate future litigation.

Neither HHS nor the AHA wish to be trapped on what Justice Ketanji Brown Jackson once called "a hamster wheel of perpetual administrative process." *Huff v. Vilsack*, 195 F. Supp. 3d 343, 364 (D.D.C. 2016). That does not benefit hospitals, their patients, or the taxpayers. Working together, HHS and the AHA can develop a fair and administrable remedy that avoids further legal or administrative delay. We look forward to discussing how to accomplish this common goal.

If you have questions or concerns in the meantime, please contact me or feel free to have members of your team contact me or AHA Deputy General Counsel Chad Golder, at cgolder@aha.org or 202-646-4624.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel and Secretary

cc:
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services