AMERICA'S ESSENTIAL HOSPITALS

February 17, 2023

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Ref: Swift Implementation of Medicare Part B Drug Cut Remedy for 340B Hospitals

Dear Secretary Becerra:

America's Essential Hospitals appreciates and supports the Department of Health and Human Services' (HHS') work to strengthen the Medicare program and protect the 340B Drug Pricing Program while working to end long-standing health inequities. The 340B program is a critical lifeline for essential hospitals, allowing these hospitals to stretch their scarce resources to improve their marginalized patients' health and meet their health-related social needs. We write to urge you to swiftly remedy five years of unlawful drug reimbursement cuts to 340B hospitals under Medicare Part B. These cuts, and a delay in recompensing hospitals for them, undermine the already precarious financial situation of essential hospitals, frustrating their ability to continue to provide lifesaving, specialized care to their communities.

America's Essential Hospitals is the leading champion for hospitals and health systems dedicated to high-quality care for all. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care, and three-quarters of their patients are uninsured or covered by Medicare or Medicaid.[1] The 340B program is key to the patchwork of federal support on which essential hospitals rely to fulfill their safety net mission. Congress established the 340B program to enable covered entities "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Simply put, 340B savings give essential hospitals financial flexibility to tailor services and programs to their community's unique challenges at nearly no cost to taxpayers.

A disproportionate number of their patients face sociodemographic challenges to health care access, including poverty, homelessness, language barriers, and low health literacy. More than 7 million people in essential hospitals' communities have limited access to healthy food, and

[1] Clark D, Ramiah K, Taylor, J, and Greig, M. *Essential Data: Our Hospitals, Our Patients—Results of America's Essential Hospitals 2020 Annual Member Characteristics Survey*. America's Essential Hospitals. September 2022. https://essentialdata.info. Accessed February 13, 2023.

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nearly 16 million live below the poverty line.[2] Essential hospitals are uniquely situated to target these social determinants of health (SDOH) and are committed to serving these marginalized patients.

Beginning in 2018, the Centers for Medicare & Medicaid Services (CMS) implemented a policy that reduced Part B drug payments to 340B hospitals by nearly 30 percent. These cuts, having been deemed unlawful by all nine justices of the U.S. Supreme Court, have been extremely damaging to essential hospitals, which treat many uninsured and underinsured patients and, as a result, operate on narrow margins. Specifically, drug payments for 340B hospitals—those most in need—have been slashed by more than $1.5 billion per year and more than $8 billion over five years. In 2021 alone, the average loss in Part B drug revenue for an essential hospital was $2.7 million.[3] These cuts are unsustainable for hospitals that already provide a disproportionate amount of uncompensated care and struggle to stay viable.

After the Supreme Court remanded the case to the lower courts, the U.S. District Court for the District of Columbia remanded the case to HHS to determine the remedy for the five years of payment cuts. CMS has indicated its plan to go through an additional round of rulemaking this year on the issue of a remedy, although the agency already has sought comments on the remedy issue multiple times before—most recently, in the calendar year 2023 Outpatient Prospective Payment System (OPPS) proposed rule. **We urge CMS to make hospitals whole for the billions of dollars in cuts as soon as possible by swiftly finalizing a remedy that conforms with the parameters we outline below.**

1. **CMS must promptly repay 340B hospitals for unlawful underpayments from 2018 to 2022, plus applicable interest.**

Given the multiple years of unlawful cuts and the delay in making 340B hospitals whole, CMS must promptly repay 340B hospitals for the losses incurred because of this policy, plus applicable interest. **There is only one way for CMS to fix the statutory violation the Supreme Court identified: promptly pay 340B hospitals the difference between the amounts previously paid for 340B drugs and the default rate of average sales price (ASP) plus 6 percent (plus applicable interest) for all years in which CMS acted unlawfully.** The Supreme Court recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support."[4] Yet, for five years, CMS deprived 340B hospitals of the benefit of the program. During that period, 340B hospitals struggled to care for patients amid a once-in-a-century pandemic. Speedy repayment to 340B hospitals is crucial. To be clear, under no circumstances should a remedy involve a new survey of acquisition costs, which not only would cause significant delay and further hardship to 340B hospitals but, worse, would ignore the Supreme Court's unanimous conclusion that a survey is a "prerequisite for varying reimbursement rates by hospital group" and its unanimous order to adopt a remedy "consistent with this opinion."[5] CMS cannot retroactively cure its past unlawful conduct with a new survey.

The remedy is straightforwardly dictated by the reasoning of the Supreme Court's decision. As noted, the Court invalidated the rate reductions for 2018 and 2019 because "the statute does

[2] Ibid.
[3] Results of analysis conducted for America's Essential Hospitals using Medicare claims, cost report, and OPPS impact file data.
[4] American Hospital Association et al. v. Becerra 596 U.S. ___, slip op. at 13 (2022).
[5] American Hospital Association et al. v. Becerra 596 U.S. ___, slip op. at 13 (2022).

not grant HHS authority to vary the reimbursement rates by hospital group."[6] The 2018 and 2019 OPPS rules that were formally before the Supreme Court did just that: they varied the payment rates for the same drugs depending on whether they were acquired by 340B hospitals and without relying on a statutorily required cost acquisition survey. The 2020, 2021, and 2022 OPPS rules did the same thing.

The Supreme Court's decision, therefore, dictates what CMS must do to fix its violations: **CMS must reimburse 340B drugs each year at the same rate used for non-340B drugs that year. For every year from 2018 through 2022, CMS already has decided the payment rate for non-340B drugs: ASP plus 6 percent. CMS needs now to match that rate for 340B drugs, a proposition with which CMS appears to agree, and include interest on these underpayments.**[7] The agency, therefore, must now craft a remedy that promptly repays 340B hospitals the difference between what they were previously paid and ASP plus 6 percent, plus interest, for CYs 2018 to 2022.

2. CMS should not seek to recoup funds from the rest of the hospital field as part of any remedy for its statutory violations.

CMS has previously invoked "budget neutrality" to argue that it may retrospectively recoup funds from hospitals as part of a remedy for its statutory violations. However, recoupment in the name of budget neutrality would be unlawful. **Nothing in federal law requires—or even authorizes—CMS to claw back funds to achieve budget neutrality**. **CMS' prior legal arguments regarding budget neutrality are contrary to the text of the OPPS statute and contravene its own past practices.**

First, the text of the OPPS statute makes clear that budget neutrality applies prospectively—not retrospectively. Budget neutrality under the OPPS is an inherently prospective exercise; it avoids increases or decreases in "overall *projected* expenditures for *the next year*."[8] Each year, the statute directs CMS to adjust the groups, relative payment weights, and wage indices in the OPPS for the upcoming year, accounting for changes in services, changes in technology, new cost data, and the like.[9] Any such changes must be budget-neutral, which means they cannot cause any change in "the *estimated amount* of expenditures . . . for the year."[10] Thus, the plain text of the statute says nothing about past years or retrospective clawbacks; instead, it only addresses future estimates and forward-looking periodic reviews.

The only provision of the OPPS statute that CMS previously cited in support of its budget-neutrality arguments is section 1395*l*(t)(14)(H).[11] But that provision relates to prospective budget neutrality and does not authorize the agency to retroactively recoup past payments as part of a remedy. Specifically, sub-paragraph (14)(H) simply requires that when CMS makes its

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[6] American Hospital Association et al. v. Becerra 596 U.S. ___, slip op. at 12 (2022).
[7] *See* CY 2023 Outpatient Prospective Payment System Proposed Rule. 87 Fed. Reg. 44502, 44647 ("We fully anticipate applying a rate of ASP+6 percent to [340B drugs] in the final rule for CY 2023, in light of the Supreme Court's recent decision."); *Am. Hosp. Ass'n v. Hargan*, No. 17-2447, ECF No. 18 at 49 (D.D.C., filed Dec. 1, 2017) (if plaintiffs were to ultimately prevail, they could obtain "an order directing [CMS] to reinstate the ASP+6% OPPS payment rate for 340B drugs").
[8] *Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (emphasis added).
[9] 42 U.S.C. § 1395*l*(t)(9)(A).
[10] *Id.* § 1395*l*(t)(9)(B) (emphasis added); *see also* 2021 OPPS Rule, 85 Fed. Reg. at 86,054 ("OPPS budget neutrality is generally developed on a *prospective* basis by isolating the effect of any changes in payment policy or data under the OPPS with all other factors held constant." [emphasis added])
[11] Defs' Opp. Brief on Remedy, *Am. Hosp. Ass'n v. Azar*, No. 18-2084, ECF No. 36 at 10 (D.D.C., filed Feb. 14, 2019).

usual prospective annual adjustments to the OPPS payment components under paragraph (t)(9) (payment groups, relative payment weights, wage adjustments, etc.), in the required budget neutral manner, CMS accounts for additional expenditures associated with implementing the paragraph (14) drug APC payment methodology. To be clear, adjustments made under paragraph (9), whether related to paragraph (14) or otherwise, apply only to the upcoming year. Sub-paragraph (14)(H) in no way authorizes CMS to retroactively recoup payments already made in the name of budget neutrality.

Nowhere does the OPPS statute speak of budget neutrality in connection with retrospective changes. During the many years it has litigated *American Hospital Association et al. v. Becerra*, CMS has never identified a clear, express reference to retrospective recoupment in the statute's budget neutrality provisions because CMS has no authority to recoup past payments to achieve budget neutrality. For example, the Supreme Court has previously stated, in the context of Medicare reimbursement, that "retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result."[12] Elsewhere, HHS has recognized that any agency authority on retroactivity must be set forth in the kind of exceedingly clear statutory language that does not exist here.[13]

Second, although CMS frequently fixes prior errors in the OPPS, America's Essential Hospitals cannot identify a single relevant instance in which CMS offset the cost of doing so by retroactively recouping prior payments to providers. Here are a few examples from across prospective payment systems of CMS fixing prior errors without recouping prior payments to achieve budget neutrality:

- In 2007, HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality, an approach the Court noted in *H. Lee Moffitt*;[14]
- In 2015, CMS realized its OPPS payments in 2014 and 2015 had been too high because it had inaccurately increased the conversion factor when it began packaging clinical diagnostic laboratory tests into its OPPS payments rather than paying for them separately using the Clinical Laboratory Fee Schedule. Upon recognizing its error, CMS reduced the conversion factor beginning in 2016 to prevent further overpayments going forward, but it did "not recoup 'overpayments' made for CYs 2014 and 2015."[15]
- Within the context of IPPS, although annual area wage index adjustments must be budget-neutral,[16] CMS can revise a wage index in response to an adverse judicial decision without a need for corresponding changes to achieve budget neutrality.[17]

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[12] *See Bowen*, 488 U.S. at 208; *see also Claridge Apartments Co. v. Comm'r of Internal Revenue*, 323 U.S. 141, 164 (1944) ("Retroactivity, even where permissible, is not favored, *except upon the clearest mandate*." (emphasis added)).

[13] *See* Gov't Memo., *H Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Price*, No. 1:16-cv-2337-TJK, ECF No. 16-1, at 25 (D.D.C., filed July 17, 2017) ("Generally, retroactive applications of a law are strongly disfavored, as they disrupt legitimate expectations and disturb settled transactions. …. Indeed, cases where the Supreme Court has truly found retroactive effect adequately authorized by a statute have involved statutory language that was so clear that it could sustain only one interpretation." [cleaned up and citations omitted]).

[14] 324 F. Supp. 3d at 15; *See also* 2007 OPPS Rule, 71 Fed. Reg. 67960, 68010 (Nov. 24, 2006).

[15] 2016 OPPS Rule, 80 Fed. Reg. 70,298, 70,354 (Nov. 13, 2015).

[16] 42 C.F.R. § 412.64(e)(1)(ii).

[17] *See id.* § 412.64(*l*).

We are aware of only a single instance when CMS, through a prospective adjustment, offset past overpayments caused by a policy change under a prospective payment system, but it did so only pursuant to express authorization from Congress. In that lone example, CMS changed certain documentation and coding policies under the IPPS for 2008 and recognized that those changes might lead to higher aggregate expenditures that did not reflect actual changes in services.[18] After CMS announced the changes, Congress acted twice to give CMS narrow, specific authority to reduce payment rates in future years to offset past overpayments caused by the policy changes.[19] Notably, Congress gave CMS express authority to apply budget neutrality, but even then, only through a prospective adjustment. Congress "knows exactly how" to give CMS express authority to offset past Medicare overpayments "when it wishes," but did not do so here. [20]

Given this statutory text and regulatory history, CMS has no authority to retrospectively recoup funds from the hospital field as part of any remedy in *American Hospital Association et al. v. Becerra*. Thus, not only would it be unfair and unwise to penalize hospitals for the agency's mistakes in this way, it would be unlawful, as well. **We urge CMS to implement a fair, effective, and lawful remedy promptly—without the cost, disruption, and distraction of many more years of litigation to finally put the prior unlawful policy behind it.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

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[18] 2008 IPPS Rule, 72 Fed. Reg. 47,130, 47186 (Aug. 22, 2007).
[19] *See* TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–97 (2007); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013).
[20] *Ysleta Del Sur Pueblo v. Texas*, 142 S.Ct. 1929, 1942 (June 15, 2022); *see generally Brimstone R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928) ("The power to require readjustments for the past is drastic. It . . . ought not to be extended so as to permit unreasonably harsh action *without very plain words*." (emphasis added)).