



August 28, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

Dear Administrator Brooks-LaSure:

On behalf of the Arizona Hospital and Healthcare Association (AzHHA) and our more than 80 hospital, healthcare and affiliated health system members, we are grateful for the opportunity to comment on the Department of Health and Human Services' (HHS) proposed remedy for its underpayments for outpatient drugs purchased under the 340B Drug Pricing Program between calendar years (CYs) 2018 and 2022 following the Supreme Court's unanimous decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022).

AzHHA strongly supports many features of the proposed remedy, including: 1) a one-time lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B program between CYs 2018 and 2022; 2) the agency's decision to include in its repayment the additional amount that hospitals would have received in beneficiary cost-sharing; and 3) the proposed methodology for calculating what 340B hospitals are owed, which minimizes administrative burden. **These features of the proposed remedy should be finalized as soon as possible.**

At the same time, AzHHA is greatly disappointed that HHS made the choice to propose "budget neutrality adjustments" to offset this legally required remedy. As persuasively explained in the American Hospital Association's (AHA) comment letter, the statutes that HHS relies on in its proposed rule do not give it the authority to make a "budget neutrality adjustment." Nor do they require budget neutrality as a matter of law. Contrary to suggestions in the proposed rule, HHS has both the legal obligation and legal flexibility to not seek a claw back of funds that hospitals received as a result of HHS' own mistakes and that hospitals have long since spent on patient care—including during the COVID-19 pandemic. **Accordingly, HHS must not pursue any "budget neutrality adjustment" in the final rule. At the very least, it must pursue a far smaller one than the proposed \$7.8 billion "adjustment."**

Please see below for additional context.

FINALIZE THE REPAYMENT PORTION OF THE PROPOSED RULE

AzHHA fully supports HHS' proposal for remedying its unlawful payment policy for 340B-acquired drugs for the period from CY 2018 through September 27 of CY 2022. The proposal to make one-time lump sum payments is undoubtedly the best remedial approach, minimizing burden for 340B hospitals and the agency. We also agree with the agency's methodology for calculating repayment amounts. Likewise, we unequivocally support HHS' proposal to pay 340B hospitals what they would have received from beneficiary cost-sharing had the unlawful 340B payment policy not been in effect. These aspects of the proposed rule advance all the relevant legal and public policy interests—adherence to the Supreme Court's decision, full and prompt repayment to 340B hospitals, administrative simplicity, patient protection, respect for the hospital field's ongoing financial challenges, and equity. **These portions of the proposed rule should be finalized as soon as possible, so that hospitals and health systems can be repaid in 2023.**

DO NOT FINALIZE THE PROPOSED "BUDGET NEUTRALITY ADJUSTMENT"

HHS is under the mistaken impression that it is either authorized or required by law to seek a "budget neutrality adjustment." HHS has made an intentional choice in the proposed rule to rely on sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act as its authority for making the remedial repayments, ostensibly so that it can then, in turn, insist that these two provisions "require" it to claw back money from hospitals and health systems in the name of "budget neutrality." But as the AHA correctly explains in its comment letter, those authorities do *not* support a repayment or the corresponding "adjustment." HHS should abandon this reverse-engineered effort to achieve recoupment. Instead, HHS should rely on its well-established authority to acquiesce in the Supreme Court's unanimous decision. This acquiescence approach is on firm legal and historical ground, will sever repayment from the recoupment in the face of potential legal challenges by 4,000 affected covered entities, and will bring all stakeholders closer to finally putting this unfortunate saga behind them.

Likewise, as the AHA explains, HHS cannot independently rely on its section 1833(t)(e) "adjustment" authority under the prospective payment system or any common law authority to effectuate a retrospective "budget neutrality adjustment." And despite using the word "adjustment" *more than 100 times* in the proposed rule, HHS lacks the legal authority to make the proposed \$7.8 billion "adjustment." As the Supreme Court recently held in *Biden v. Nebraska*, a statutory "adjustment" must be moderate or minor. But a \$7.8 billion retrospective claw back from all outpatient prospective payment system (OPPS) entities is anything but moderate or minor. It is likely that HHS did not have time to factor in this Supreme Court decision when issuing its proposed rule, but its final rule must account for it.

Consequently, even if HHS had the legal authority to pursue a "budget neutrality adjustment" at all—and it does not—then it must, at a minimum, drastically reduce or modify its proposal in the final rule to better align with the "minor" adjustments permitted by statute. In particular, in these "unique circumstances," as HHS rightly calls them, it should consider: 1) making only a

\$1.8 billion “adjustment” to correspond to the cost-sharing repayments the agency proposes (and should finalize); and 2) not including CYs 2020-2022 in any “adjustment” because recouping funds that hospitals spent caring for patients during a once-in-a-century pandemic is not “equitable” under the statute (or, for that matter, sensible public policy).

In addition to these legal defects, HHS’ policy justifications do not support a “budget neutrality adjustment.” The agency’s repeated reference to a “windfall” completely ignores its own role in creating this situation. When the agency implemented its unlawful policy and continued to defend it for many years, hospitals in Arizona had no choice but to accept these funds. We should not be adversely impacted in the future by the agency’s own unlawful actions in the past.

The agency also overstates the financial risk to the Supplementary Medicare Insurance (SMI) Trust Fund, which is at no risk of insolvency, and ignores the moral hazard problem it creates by permitting retrospective recoupment in circumstances like these. If HHS had been told years ago that it could not recoup funds from hospitals to make up for its unlawful cuts, one wonders whether the agency would have continued to implement and defend its illegal policy for so long?

Finally, the proposed rule errs by largely ignoring the current financial state of America’s hospitals and health systems. Hospitals still feel the financial effects of COVID-19, and clawing back funds would be inconsistent with President Biden’s promises to hospitals and health care workers: “Our doctors, nurses, hospital staffs have gone above and beyond during this pandemic. The strain and stress is real. I really mean it. It’s real. And we’ll have their backs though. We have to let them know we have their backs.” Remarks by President Biden on the Fight Against COVID-19 (Dec. 21, 2021), at <https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/12/21/remarks-by-president-biden-on-the-fight-against-covid-19/>. As America’s hospitals and health systems struggle to dig out of the pandemic, their margins remain well below historical norms. **At a minimum, HHS should delay implementation of any “adjustment” until CY 2026 (at the earliest) so that hospitals are given more time to recover financially from the pandemic.**

Hospitals and health systems also continue to suffer from systemically inadequate Medicare reimbursement. Medicare pays hospitals, on average, 84 cents for every dollar of care provided, and those underpayments have caused hospital Medicare margins for outpatient care to be a staggering *negative 17.5%*. What’s more, hospitals’ total costs increased 17.5% between 2019 and 2022, while government reimbursement for care provided under Part B increased by only 7.2%. **Clawing back funds from hospitals and health systems would constitute a conscious choice by the Administration to make a deeper Medicare cut, creating additional ongoing financial challenges for hospitals and health systems across the country.**

In the end, the legal and public policy reasons that HHS offers do not support its choice to seek the proposed “budget neutrality adjustment.” To be clear, we appreciate HHS’ attempt to draft an “offset [that] is not overly financially burdensome on impacted entities,” including by

proposing a prospective 16-year offset period with a delayed start. **If HHS chooses to pursue a “budget neutrality adjustment,” it should not abandon these features. But for the reasons explained above and in the AHA’s comment letter, HHS must not pursue *any* “budget neutrality adjustment” in the final rule, or, at the very least in these “unique circumstances,” it must pursue a far more modest one than the proposed \$7.8 billion “adjustment.”**

ADDRESS THE MEDICARE ADVANTAGE ORGANIZATION (MAO) WINDFALL

Although it is potentially outside the scope of this proposed rule, we urge HHS to take all possible measures within its authority to ensure MAO compliance with the remedy so that these entities do not receive an inadvertent windfall. On December 20, 2022, CMS sent a reminder to MAOs about the Supreme Court’s decision in *American Hospital Association v. Becerra* and the district court’s September 28, 2022 order vacating the differential payment rates for 340B-acquired drugs in the CY 2022 OPPS final rule. Since then, MAOs have not appropriately respected those decisions by repaying hospitals what they are owed. HHS should continue to press MAOs to make their legally required repayments. One option going forward is for HHS to use its prompt payment authorities under 42 U.S.C. 1395w-27(f) to ensure MAO compliance with this remedy.

At a minimum, the agency must account for the MAO windfall that will result from the proposed -0.5% adjustment to payment rates, especially if the MAOs continue to refuse to pay the difference between the unlawful 340B policy amounts and what hospitals are owed. This windfall to MAOs does not advance the agency’s stated primary public policy objective, *i.e.*, lessening the impact of HHS’ past mistakes on the SMI Trust Fund. And with more than half of Medicare beneficiaries enrolled in an MAO, the potential scale of the recoupment from hospitals could potentially *double* but would only serve to pad MAO’s skyrocketing profits.

The complications associated with this windfall provides yet another reason why HHS should not pursue a “budget neutrality adjustment.” If HHS makes the misguided decision to seek one, however, it must craft a recoupment that addresses this MAO double-dipping problem. **Whether it is lowering the overall “adjustment” amount to account for the MAO windfall or finding another way to recoup funds that forecloses it (*e.g.*, through a cost report reconciliation rather than through the payment rate or PRICER), HHS cannot ignore this problem in the final rule.**

Finally, AzHHA recommends opening the program for tax-paying hospitals, while increasing the amount of funding so non-profit hospitals to maintain their existing programs. There are numerous hospitals across the country that would qualify for the 340B program but are prohibited because of their ownership status. Prohibiting tax-paying hospitals’ participation undermines the program’s intent “to provide more patients with more services.” Many tax-paying hospitals provide great levels of charity care.

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In sum, HHS should finalize the repayment aspects of the proposed rule as soon as possible, and it should not pursue any “budget neutrality adjustment.” But if it does seek a retrospective claw back, HHS should: 1) drastically reduce the overall amount; 2) delay any recoupment until 2026 or later; 3) finalize the current aspect of the proposal that would spread the “adjustment” across 16 years (or more); and 4) recoup funds in a way that does not lead to a MAO windfall at the expense of hospitals and health systems, which in no way benefits the SMI Trust Fund.

Thank you for the opportunity to comment on this rulemaking. Please feel free to contact me with any questions.

Sincerely,

A handwritten signature in black ink that reads "Amy Upston". The signature is written in a cursive, flowing style.

Amy Upston
Director of Financial Policy and Reimbursement
Arizona Hospital and Healthcare Association

Phone
602-445-4300
Fax
602-445-4299

2800 N. Central Ave., Suite
1450
Phoenix, AZ 85004