August 31, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, D.C. 20201

Re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (RIN 0938-AV18)

Dear Administrator Brooks-LaSure:

On behalf of the Indiana Hospital Association (IHA), which was founded in 1921 and represents 170 hospitals across Indiana to advance a health care delivery system that improves the health of all Hoosiers, 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).

IHA 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, IHA is greatly disappointed that HHS made the choice to propose "budget neutrality adjustments" to offset this legally required remedy. As further 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. **Accordingly, HHS must not pursue *any* "budget neutrality adjustment" in the final rule.**

FINALIZE THE REPAYMENT PORTION OF THE PROPOSED RULE

IHA fully supports HHS' proposal for remedying its unlawful payment policy for 340B-acquired drugs between CYs 2018 and 2022. The proposal to make one-time lump sum payments is undoubtedly the best remedial approach, minimizing burden for 340B hospitals, and IHA is supportive of HHS' proposed methodology. Likewise, IHA supports 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 of 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 in turn insist that these two provisions "require" the agency to claw back money from hospitals and health systems in the name of "budget neutrality." Instead, HHS should rely on its well-established authority to acquiesce to the Supreme Court's unanimous decision. This acquiescence approach is on firm legal and historical ground, will sever repayment from recoupment in the face of potential legal challenges by 4,000 affected covered entities, and will bring all stakeholders closer to a final remedy.

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," which runs counter to the finality and predictability principles that are foundational to the Medicare outpatient prospective payment system (OPPS). Further, HHS lacks the legal authority to make the particular proposed $7.8 billion "adjustment." As the Supreme Court recently held in *Biden v. Nebraska*, a statutory "adjustment" must be moderate or minor. A $7.8 billion retrospective claw back from all OPPS entities, whether or not they participate in the 340B program, 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.

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 had no choice but to accept these funds and should not be adversely impacted in the future for the agency's own unlawful actions in the past.

Finally, the proposed rule errs by largely ignoring the current financial state of America's hospitals and health systems following the COVID-19 public health emergency. **Indiana hospitals operated on a -2% margin last year and have lost billions in days of cash on hand since the pandemic – an average 20% decline across the state. The "budget neutrality adjustment" will only continue to exacerbate the negative financial environment that Indiana hospitals are currently experiencing, including urban and rural safety net hospitals.**

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 these 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.**

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. On December 20, 2022, CMS sent a reminder to MAOs about the Supreme Court's decision in Am*erican Hospital Association v. Becerra* and the district court's order vacating the differential payment rates for 340B-acquired drugs in the CY 2022 OPPS final rule. Since then, MAOs have not fully adhered to those decisions by repaying hospitals what they are owed. HHS should continue to press MAOs to make their own 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 gain 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. And with more than half of Medicare beneficiaries enrolled in an MAO, the potential scale of the recoupment from hospitals would only serve to pad MAO's skyrocketing profits, providing yet another reason why HHS should not pursue a "budget neutrality adjustment."

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.

Sincerely,

Laura Brown
Deputy General Counsel
Indiana Hospital Association