WISCONSIN HOSPITAL ASSOCIATION

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September 8, 2023

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

Re: Medicare Program CMS–1793–P; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022 (RIN 0938-AV18) (July 11, 2023)

Dear Administrator Brooks-LaSure:

On behalf of our more than 150 member hospitals and integrated health systems, the Wisconsin Hospital Association (WHA) appreciates the opportunity to provide comments 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).

WHA was established in 1920 and is a voluntary membership association. We are proud to say we represent all of Wisconsin's hospitals, including small Critical Access Hospitals, mid, and large-sized academic medical centers. We have hospitals in every part of the state—from very rural locations to larger, urban centers like Milwaukee. In addition, we count close to two dozen psychiatric, long-term acute care, rehabilitation and veterans' hospitals among our members.

WHA 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, WHA continues to urge HHS to abandon its pursuit of "budget neutrality adjustments" to offset this legally-required remedy. As WHA has previously asserted in past comment letters, and as the American Hospital Association's (AHA) has stated in its own 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 is not required to seek a clawback 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. In fact, it has a legal obligation not to do so.

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." This is especially important when one considers the immense fiscal pressures hospitals are in as a result of record inflation, workforce shortages that are driving up wages, and skyrocketing drug price increases. Medicare already underpays hospitals – with the average Wisconsin hospital receiving only about 73% of what it costs to deliver care – and recent updates

to Medicare's outpatient reimbursement scheme have fallen well below real cost increases for hospitals. CMS's proposal to claw back funds into the future will only exacerbate these challenges for hospitals.

Finalize the Repayment Portion of the Proposed Rule While Giving Hospitals an Opportunity to Appeal HHS's Calculation of Repayment Amounts

WHA 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 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.**

Additionally, HHS must give hospitals additional time to appeal the repayment amounts listed in the data file while allowing hospitals the opportunity to submit data justifying an alternative repayment amount. WHA has heard from Wisconsin hospitals who have calculated a different amount than what appears in the data file. HHS should provide more transparency about the data utilized to calculate the amounts in the data file.

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 WHA has previously stated and 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 in its comment letter, 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 particular 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 clawback 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 like WHA's members had *no choice* but to accept these funds. They should not be adversely impacted in the future for 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."[1] 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.

An April 2023 report released by the American Hospital Association highlights some of the cost increases hospitals are bearing right now:

- From 2019-2022 hospital expenses grew by 17.5% compared to IPPS increases of 7.5%.
- Meanwhile, hospitals have had little choice but to turn to contract labor to fill shifts, which led to an increase on contract labor costs by 258% over the same time period.
- Drug costs increased by 37% from 2019-2021, and by even more for 340B hospitals who are no longer receiving the full level of discounts for patients served by community contract pharmacies.

Despite numerous financial pressures, hospitals have worked hard in recent years to keep costs down. According to data from the Bureau of Labor Statistics, hospital prices have grown an average of 2.1% per year over the last decade, about half the average annual increase in health insurance premiums. However, with the combination of historic inflation, an unprecedented workforce shortage, and sustained underpayments by federal government health care programs, hospitals are facing significant fiscal pressures going forward.

Unfortunately, CMS's payment system does not reward Wisconsin hospitals for keeping costs down: Wisconsin ranks 16th lowest in terms of per-beneficiary spending according to the Kaiser Family Foundation, and yet, Wisconsin hospitals receive, on average, around 73% of what it costs them to provide Medicare services, well below the national average of about 84% of costs. At the same time, Wisconsin is also the 16th highest state in terms of the percent of its population on Medicare. As people move off private insurance and onto Medicare, it compounds the impact of insufficient Medicare reimbursements, as Wisconsin has seen annual Medicare underpayments for WI hospitals grow from $1.77B in 2016 to $2.53B in 2021 – a 42% increase. This trend is

[1] 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/

only projected to increase given that Wisconsin is an aging state. In fact, as of 2018, Wisconsin was tied for 16th among states with the highest percent of their population covered by Medicare, at 20%.[2]

What's more, hospitals are increasingly are not being reimbursed for long patient stays and post-acute care they are providing. The average length of a patient stay increased 9.9% by the end of 2021 compared to pre-pandemic levels in 2019, leading hospitals to have to devote more staff time and expenses per patient episode. On top of this, Wisconsin hospitals lost an estimated $465 million in uncompensated care from patients they have not been able to discharge due to the lack of available nursing home beds – patients hospitals are not receiving reimbursement for after their hospital care concludes.

These factors have created a perfect storm of circumstances where hospitals are being significantly underfunded by the nation's safety-net Medicare and Medicaid programs. When one considers that Medicare and Medicaid make up more than half of inpatient care for 94% of Wisconsin hospitals, it shows just how challenging this dynamic is becoming.

Unlike other industries, hospitals cannot simply raise prices to bring in additional revenue. Hospitals can only bring in additional revenue by renegotiating higher payments with employers and health insurers, something that is increasingly difficult in the current fiscal environment. Likewise, unlike other businesses, hospitals do not have the luxury of closing down the overnight shift when operating becomes unprofitable. If hospitals are unable to grow revenue from other sources, they must make cuts to important service lines just like any other business to remain financially viable, and indeed, many are already exploring this reality. Policies like CMS is pursuing in this proposed remedy to unexpectedly recoup funding only exacerbate these challenges.

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, HHS must abandon its proposed "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 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 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

[2] Wisconsin Department of Administration. Percent of Projected Population Ages 60 and Older. [Online] 2017. https://www.dhs.wisconsin.gov/publications/p01803.pdf

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.**

In summary, 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 clawback, 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.

WHA appreciates the opportunity to provide comments on this proposed rule.

Sincerely,

Eric Borgerding
President & CEO