AHPA
ADVENTIST HEALTH
POLICY ASSOCIATION

September 5, 2023

The Honorable Administrator 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 Adventist Health Policy Association, (AHPA) 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).

AHPA represents a major segment of the U.S. hospital sector. Our member hospitals operate in a variety of settings, ranging from rural Appalachia to urban areas of California. Many of our facilities rely substantially on savings from the 340B program to increase access to health care services and address specific community needs. With such diverse facilities, populations served and geographic locations, we strive to provide objective and sound policy recommendations that work well for health care as a whole.

AHPA strongly supports the comments submitted by the American Hospital Association (AHA). Specifically, we support finalizing several 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) including in the 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. **We believe these features of the proposed remedy should be finalized as soon as possible so that hospitals receive their lump sum by the end of CY 2023.**

At the same time, we are disappointed that HHS made the choice to propose "budget neutrality adjustments" to offset this legally-required remedy by reducing the OPPS conversion factor by 0.5% every year beginning in CY 2025 until the previous budget neutrality adjustment of $7.8 billion is reached. We believe 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. Just last year, in a similar situation where CMS mistakenly had overpaid hospitals with affiliated nursing school programs, Congress passed the TRAIN Act which barred the agency from recouping those dollars and ordered CMS to refund monies the agency had already recouped.

HHS is relying on sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act as its authority for making the remedial repayments but as the AHA explains in its comment letter, those authorities do *not* support a repayment or the corresponding "adjustment." Therefore, HHS should abandon this budget-neutrality approach and should instead 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 issue behind them.

Likewise, 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." Despite using the word "adjustment" 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 entities is anything but moderate or minor. 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, HHS 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.

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. Hospitals like the ones impacted within AHPA had *no choice* but to accept these funds. Health providers should not be adversely impacted in the future for the Agency's own mistakes, particularly if those actions were found unlawful.

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 the COVID-19 pandemic and continue to struggle due to the nationwide workforce shortages. These shortages are requiring health care providers to make additional investments to retain and recruit clinicians, as well as expand the reach of the current workforce through investments in virtual technology. These efforts, coupled with increasing drug costs, pose significant financial challenges to many hospitals. A report from the Center for Healthcare Quality and Payment Reform (CHQPR) found that over 600 rural hospitals are at risk of closing in 2023.[1] Due to these issues, **at a minimum, HHS should delay implementation of any "adjustment" until CY 2026 so that hospitals are given more time to recover financially. If such "adjustment" is implemented, we support the proposed policy of phasing the payment cuts.**

Potential Unintended Consequence:
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 Am*erican 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, failing to repay 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 payment reductions and what hospitals are owed. The complications

[1] Center for Healthcare Quality and Payment Reform. Rural Hospitals at Risk of Closing.

associated with this windfall provides yet another reason why HHS should not pursue a "budget neutrality adjustment." However, if HHS makes the decision to seek one, it must craft a recoupment that addresses this MAO double-dipping problem. This could involve lowering the overall "adjustment" amount to account for the MAO windfall or finding another way to recoup funds (*e.g.*, through a cost report reconciliation rather than through the payment rate or PRICER).

Conclusion

AHPA shares HHS' goal of ensuring access to care for marginalized communities, like those served by 340B hospitals. We specifically believe that HHS should finalize the repayment aspects of the proposed rule as soon as possible, but it should not pursue any "budget neutrality adjustment." Should the Department still seek a retrospective clawback, HHS should:

1) 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.

If you have any questions or would like further information, please do not hesitate to contact me or Susana Molina Ramos, Director of Public Policy, at Susana.MolinaRamos@adventisthealthpolicy.org.

Sincerely,

Michael E. Griffin
President
The Adventist Health Policy Association