September 1, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue, S.W.
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)

Submitted electronically via http://www.regulations.gov

Dear Administrator Brooks-LaSure:

Trinity Health appreciates 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).

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 123,000 colleagues and over 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is $21.5 billion with $1.4 billion returned to its communities in the form of charity care and other community benefit programs.

The 340B Drug Savings Program provides essential resources that are critical to helping 340B hospitals comprehensively serve the most vulnerable and improve the health of communities. Trinity Health has 31 340B programs operating in 14 states that support services to improve patient care, increase patient medication access and adherence and decrease hospital readmissions. Trinity Health submits these comments to express support and concerns regarding the issues addressed below.

Trinity Health 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, Trinity Health is disappointed that HHS made the choice to propose "budget neutrality adjustments" to offset this legally required remedy. 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 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. Accordingly, HHS should not pursue any "budget neutrality adjustment" in the final rule. At the very least, it should pursue a far smaller one than the proposed $7.8 billion "adjustment."

Finalize the Repayment Portion of the Proposed Rule

Trinity Health 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 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 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.

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 a 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 those authorities do not support a repayment or the corresponding "adjustment." HHS should abandon this 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.

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." 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 not 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, 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).

Finally, the proposed rule errs by largely ignoring the current financial state of America's hospitals and health systems. As America's hospitals and health systems struggle to dig out of the pandemic, our 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, 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 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 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.

Conclusion

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) 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 provide comments on the proposed remedy for its underpayments for outpatient drugs purchased under the 340B Drug Pricing Program between calendar years (CYs) 2018 and 2022. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health