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September 5, 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) (July 11, 2023), CMS–1793–P

Dear Administrator Brooks-LaSure:

On behalf of our more than 200 member hospital and health systems, Florida Hospital Association (FHA) appreciates the Department of Health and Human Services' (HHS) attentive approach to the proposed remedy following the Supreme Court's decision in *American Hospital Association v. Becerra,* 142 S. Ct. 1896 (2022).

The FHA strongly supports many features of the proposed remedy, including: 1) a onetime lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B Drug Pricing Program between calendar years (CYs) 2018 and 2022; 2) the agency's decision to repay what hospitals would have received in beneficiary cost-sharing; and 3) the proposed methodology for calculating what 340B hospitals are owed, which minimizes administrative burden. Since the Supreme Court issued its decision, the FHA and its partners at the American Hospital Association have advocated for full and prompt repayment of 340B hospitals because they, like other hospitals in the field, are weathering significant financial challenges. The proposed remedy achieves this goal. **These features should be finalized as soon as possible.**

At the same time, FHA is greatly disappointed that HHS chose 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 clawback of funds that hospitals received, and have since spent, as a result of HHS' own mistakes. **Accordingly, HHS must not pursue any "budget neutrality adjustment" in the final rule. If HHS pursues a**

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clawback at all, it should be significantly smaller than the $7.8 billion described in the proposed rule.

FINALIZE THE REPAYMENT PORTION OF THE PROPOSED RULE

FHA fully support HHS' proposal for remedying is unlawful payment policy for 340B-acquired drugs for the period from CY 2018 through September 27 of CY 2022. The proposal to make onetime 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 asserts that it is either authorized or required by law to seek a "budget neutrality adjustment," however, we disagree with their interpretation and believe the agency is relying on the wrong sections of the Social Security Act (Act) (1833(t)(2)(E) and 1833(t)(14)) to state their obligations. As the AHA explains in its comment letter on the proposed rule, those sections of the Act do not support a repayment or the corresponding budget neutrality adjustment. HHS should disregard these sections of law, and instead rely on the well-established authority to acquiesce in the Supreme Court's unanimous decision. The doctrine of acquiescence allows HHS to sever repayment from the recoupment in the face of potential legal challenges by some 4,000 stakeholders.

Likewise, the AHA explains, HHS cannot independently rely on section 1833(t)(2)(E) of the Act for "adjustment" authority under the prospective payment system or any common law authority to effectuate a retrospective "budget neutrality adjustment." In fact, HHS lacks any legal authority to make the proposed $7.8 billion "adjustment" based on the Supreme Court decision in *Biden v. Nebraska*, which makes clear that any adjustment by an agency must be moderate or minor and that larger adjustments should be reserved for the Congress. A $7.8 billion retrospective clawback from all OPPS entities is obviously not minor or moderate. As the court ruled on this nearly concurrently with the release of the proposed rule, we do not expect that HHS considered their ruling, however, they must factor in the court's decision in its final rule.

Consequently, even if HHS had the legal authority to pursue a "budget neutrality adjustment" at all—and we do not believe it does —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 Florida had no choice but to accept these funds. Those providers should not be adversely impacted in the future by the agency's own unlawful actions in the past.

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 MEDICARE ADVANTAGE ORGANIZATION (MAO) UNDERPAYMENTS

FHA urges 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 responded to those decisions by repaying hospitals for years of underpayments based on an illegal policy. HHS should continue to press MAOs to repay covered entities for the underpayments during the period of CMS's unlawful 340B policy. 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 an MAO windfall that could result from the proposed -0.5% adjustment to payment rates, especially are unable to negotiate a repayment of the difference between the unlawful 340B policy amounts and what hospitals are owed. This excess revenue 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 (nearly 60% in Florida), the potential scale of the recoupment from hospitals could potentially double.

The complications associated with how MAO plans should respond to HHS's unlawful policy provides yet another reason why HHS should not pursue a "budget neutrality adjustment." If HHS decides 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, HHS cannot ignore this problem in the final rule.**

HHS should finalize the repayment aspects of the proposed rule as soon as possible and it should not pursue any budget neutrality adjustment. To the extent the agency moves forward with clawbacks it must 1) reduce the total overall amount recouped; 2) delay any recoupment until 2026 or later; 3) finalize the current aspects of the proposal that would spread the unnecessary budget adjustment over 16 years; and 4) recoup funds in a way that does not lead to excess revenue being paid to MAO at the expense of hospitals, health systems and the patients they serve.

Thank you for the opportunity to provide these comments. If you have any questions please do not hesitate to contact me or Michael Williams at michaelw@fha.org.

Sincerely,

Mary C. Mayhew
President and CEO
Florida Hospital Association