September 7, 2023

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-1793-P
P.O. Box 8010
Baltimore, Maryland 21244-8010
Submitted Electronically: regulations.gov

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)

Dear Administrator Brooks-LaSure:

On behalf of our over 470 member hospitals and health systems, including rural, urban, children’s, teaching, and specialty hospitals, the Texas Hospital Association (“THA”) appreciates the opportunity to provide comments on the above-referenced proposed rule, following the Supreme Court’s decision in American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022). In parallel with AHA’s previously submitted comments, THA supports the proposed remedy regarding lump sum payments but opposes the “budget neutrality adjustments.”

THA strongly supports 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 FYs 2018 and 2022; (2) the decision to include 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 for those hospitals. These aspects of the proposed remedy should be finalized as soon as possible.

However, THA opposes the proposed “budget neutrality adjustments” as HHS’ attempt to offset the legally required remedy. The statutes HHS relies on – sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act – do not provide authority for a “budget neutrality adjustment,” nor do they require budget neutrality as a matter of law. An external analysis reviewed by THA estimates the proposed rule will result in Texas facing net losses over the next 16 years, with nearly 300 Texas hospitals losing approximately $299 million through 2040. This is a significant negative effect. We strongly urge HHS to reconsider and eliminate the “budget neutrality adjustments”.

1. THA supports the proposed lump sum repayment.

THA supports HHS’ proposal to immediately pay hospitals a lump sum under the 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 now overturned 340B payment policy not been in effect. These aspects of the proposed rule advance 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 as soon as possible.**

2. **THA does not support the proposed “budget neutrality adjustment.”**

Hospitals had to accept funds under the now overturned payment policy. Texas hospitals should not suffer adverse impacts because of this proposed payment scheme. For example, certain facilities should not obtain a double benefit from both a lump sum payment and increased, adjusted payment rate, nor should other facilities receive a minimal payment and face a decreased payment rate.

The cited portions of the Social Security Act do not support repayments or adjustments. Instead, HHS should rely on its well-established authority to follow the Supreme Court’s unanimous decision. This approach is on firm legal and historical ground and will sever repayment from the recoupment in the face of potential legal challenges by 4,000 affected covered entities. Likewise, as AHA set forth in its comments, 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” over 100 times in the proposed rule, HHS lacks the legal authority to make the 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 claw back from all outpatient prospective payment system (OPPS) entities is neither moderate nor minor.

THA fully incorporates the AHA’s comments and encourages HHS to revise the remedy to include AHA’s recommendations.

THA appreciates 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, but the legal and public policy reasons offered do not support HHS’ choice to seek the proposed “budget neutrality adjustment.” **If HHS chooses to pursue a “budget neutrality adjustment,” it should not abandon these features. However, for the reasons explained above and in the AHA’s comment letter, HHS must not pursue any “budget neutrality adjustment” in the final rule.**

Sincerely,

Cesar J. Lopez
Associate General Counsel
Texas Hospital Association