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August 19, 2022

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: CMS-1772-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, July 26, 2022.

Dear Administrator Brooks-LaSure:

On behalf of the Suburban Hospital Alliance of New York State, which represents hospitals in New York's Hudson Valley and on Long Island, we are grateful for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS) for calendar year (CY) 2023. Our comments here address CMS' proposal regarding Medicare Part B payments for drugs acquired under the 340B drug pricing program for CY 2023, as well as the agency's request for comment on a remedy following the Supreme Court's unanimous decision in *American Hospital Association v. Becerra*.

As you are aware, earlier this summer, the U.S. Supreme Court unanimously struck down CMS' policy of varying reimbursement rates for 340B hospitals. As such, **we support the agency's position that it "fully anticipates" reverting to its prior policy of paying Average Sales Price (ASP) plus 6% for 340B-acquired drugs in CY 2023 and urge it to finalize this policy in the OPPS final rule.**

CMS also has requested comments on a remedy in *American Hospital Association v. Becerra*. As we explain below, the Supreme Court's decision dictates that the only possible remedy is to:

1. Revert to the prior lawful policy of paying ASP plus 6% for CY 2023, regardless of whether a drug was acquired through the 340B program;
2. Promptly repay any hospital the difference between ASP plus 6% and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022; and
3. Hold the entire hospital field harmless for this illegal policy for CYs 2018-2022, which means no recoupment of funds received during this period.

We strongly encourage CMS to agree to this remedy in the ongoing *American Hospital Association v. Becerra* litigation and to ensure that payments to hospitals are appropriately restored in the agency's CY 2023 OPPS final rule.

Complete and Prompt Repayment Is Necessary
To correct the unlawful policy that the Supreme Court struck down, the agency should promptly repay 340B hospitals the difference between ASP plus 6% and the amount actually paid to hospitals for 340B drugs (plus applicable interest) for *all* the years in which the agency acted unlawfully. The Supreme Court recognized that "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." Yet for five years, CMS' unlawful policy has deprived 340B hospitals of payment, even as hospitals across the country struggled to care for their patients and communities amidst a once-in-a-century pandemic.

The survey of 340B acquisition costs initiated in CY 2020 was defective and as such cannot be used to set future payment rates, or to delay or deny repayment for CYs 2021 or 2022. That survey does not comport with the law and was never relied upon by the agency as the basis for continuation of its unlawful policy. It is not a fair, proper, or legal basis for the agency to delay or deny repayment.

Retrospective Recoupment Would Be Unfair, Unlawful and Unprecedented
In the past, CMS has raised the specter of invoking "budget neutrality" to retrospectively recoup funds from hospitals that received them because of its unlawful policy. However, the agency should *not* penalize any hospital for the agency's own past mistakes in implementing an unlawful policy. Not only would retrospective recoupment be illegal, it would be impossible to implement as a practical matter. Most of the funds that hospitals received were already spent during the pandemic, a crisis that even today is causing hospitals to struggle financially. Clawing back those funds would only further put patients and communities at risk.

Moreover, nothing in federal law requires — or even permits — CMS to claw back funds to achieve budget neutrality. The law governing the OPPS makes it clear that budget neutrality applies *prospectively* — not retrospectively — as it addresses only future estimates and forward-looking periodic reviews. Therefore, CMS lacks the legal authority to recoup past payments to achieve budget neutrality and, to the best of our knowledge, there is no relevant instance where CMS has even tried to recoup prior OPPS payments.

Finally, it is important to keep in mind that the agency exempted a number of 340B hospitals from its unlawful policy, including rural sole community hospitals, free-standing children's hospitals and free-standing cancer hospitals. Not only would it appear that these hospitals would be subject to claw backs, but it would be impossible to fairly implement a budget neutrality policy if these entities were not subject to the same recoupments as other hospitals. Neither these exempted hospitals nor any others should be subject to claw backs based on an illegal policy that has already disrupted the entire hospital field during arguably the most vulnerable period in its history.

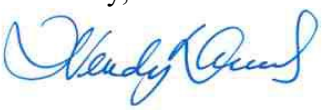
Concerns Regarding CY 2023 Conversion Factor Adjustment and Reporting of Claims Modifiers
For CY 2023, CMS states that it "fully anticipates" restoring payment to 340B hospitals at a rate of ASP plus 6% for separately-payable drugs. In undoing the agency's unlawful policy, CMS is proposing a new budget neutrality adjustment to the OPPS conversion factor to account for this increase in payment. We have concerns, however, that the agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals. These payments are critical for us to cover the costs associated with caring for Medicare patients. In fact, according to the most recent report by the Medicare Payment Advisory Commission (MedPAC), hospitals' Medicare margins were *negative* 8.5% in 2020, even after accounting for federal relief during the pandemic. Hospitals

simply cannot afford to endure further underpayments. **Therefore, we urge CMS to correct the proposed adjustment to ensure that the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.**

On a related matter, we also ask the agency to abandon its policy of requiring certain hospitals to report the informational "JG" and "TB" modifiers to identify separately-payable drug claims. When the agency first proposed its unlawful 340B payment policy in the CY 2018 OPPS proposed rule, it required certain hospitals to report these modifiers on drug claims. But given that the agency fully anticipates to abandon its current 340B payment policy, there is no need for the agency to continue to collect such information from hospitals. In fact, abandoning the use of these modifiers would be consistent with CMS' ongoing commitment to reduce regulatory burden for providers. **Therefore, we urge the agency to no longer require hospitals to report these modifiers for CY 2023 and subsequent years.**

In conclusion, we appreciate CMS' decision to restore payment to 340B hospitals for CY 2023 in light of the Supreme Court's decision in *American Hospital Association v. Becerra*. However, we urge the agency to ensure no further harm is done to any hospital by promptly paying 340B hospitals the funds they are rightfully owed and not unfairly, unlawfully and unprecedentedly recouping any funds from hospitals who were paid as part of the agency's own unlawful policy.

Sincerely,



Wendy D. Darwell
President and CEO