September 13, 2022

[Submitted electronically to www.regulations.gov]
Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
P.O. Box 8010
Baltimore, MD 21244-1850.

Re: Docket No. CMS-1772-P for "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."

Dear Administrator Brooks-LaSure:

ASHP is pleased to submit comments to the Center for Medicare & Medicaid Services (CMS) regarding the proposed changes to the hospital outpatient prospective payment system (OPPS) for calendar year 2023 (the "OPPS rule"). ASHP is the collective voice of pharmacists who serve as patient care providers in hospitals, health systems, ambulatory clinics, and other healthcare settings spanning the full spectrum of medication use. The organization's more than 60,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 80 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP thanks CMS for the opportunity to comment on the proposed rule. We hope that our feedback will assist CMS in refining the OPPS to meet our shared patient care and quality goals.

I. Restoring 340B Reimbursement Cuts

ASHP's comments 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*.

ASHP fully supports CMS's proposal, following the Supreme Court ruling, to revert to its prior policy of paying Average Sales Price (ASP) plus 6% for drugs purchased under the 340B program. In addition to rescinding its prior cuts for hospitals and their outpatient departments, in the interest of patient care and access, CMS should refrain from any future reductions to the ASP plus 6% rate for hospitals and their outpatient departments. Such cuts represent a clear threat to patient access to services, and in some cases, to the financial stability of safety-net providers.

Regarding CMS's request for a remedy to the 340B underpayments from CY 2018 – 2022, we urge CMS to adopt a remedy that does all of the following:

- Ensures that calculation of the remedy does not add to administrative burdens on hospitals;
- Avoids reducing payment for outpatient services as a means to remedy 340B underpayments;
- Directs managed care plans that adopted CMS's cuts to 340B reimbursement to make covered entities whole for those underpayments; and
- Removes the JG modifier, as without the differential payment for 340B drugs, there is no reason to separately track 340B claims.

We address each on these elements in greater details in our comments below.

A. Any Remedy Should Be Prompt and Without New Administrative Burden

ASHP urges CMS to adopt a remedy that will quickly and fully compensate hospitals for the 340B underpayments from 2018 – 2022. Specifically, we recommend that CMS consider an attestation approach, whereby hospitals would submit attestation of the amount of underpayment for each calendar year in which they were paid the ASP plus 6% rate. CMS would then review the attestations and promptly remit the full amount of the underpayment due to each hospital.

CMS cannot use its 2020 survey to justify reducing payment rates for 2021 and 2022. CMS's 2020 survey of 340B acquisition costs was defective and therefore 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.

Finally, CMS's unlawful 340B reimbursement cut was also adopted by managed care plans and some private payors. For hospitals to attain a true and full remedy, CMS should direct managed care plans that adopted CMS's cuts to make covered entities whole for those 340B underpayments.

B. Any Remedy Must Not Require Cuts to Reimbursement for Outpatient Services

CMS has previously suggested that restoration of 340B reimbursement to ASP plus 6% would require the agency to recoup funds from hospitals on the basis of maintaining budget neutrality. However, there is simply no legal justification for any CMS attempt to try to retroactively claw back reimbursement for outpatient services. CMS's 340B policy was illegal – and the agency alone should bear the responsibility for its mistake. Not only would any such retrospective claw back be contrary to law, it would also be impossible to implement. Hospitals have long since used those payments for outpatient services to provide outpatient services. Any attempt to strip hospitals of reimbursement for services already rendered would do irreparable harm to hospitals that are only now emerging from the shadow of the COVID-19 pandemic.

Moreover, nothing in federal law requires — or even permits — CMS to claw back funds to achieve budget neutrality. The law governing Part B reimbursement contemplates only future payment, with no mention of retrospective recoupments, suggesting that budget neutrality applies only prospectively. 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 note 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.

C. *Remove the JG Modifier*

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 abandoning its current 340B payment policy, there is no need for CMS to continue to collect such information from hospitals. In fact, abandoning the use of these modifiers would be consistent with CMS's ongoing commitment to reduce regulatory burden for providers. Therefore, we urge CMS to rescind the JG and TB modifiers for 2023 and subsequent calendar years

II. Maintaining COVID-19 Regulatory Flexibilities

We strongly support CMS's proposal to pay for remote behavioral health services as a covered service under OPPS. We further encourage CMS to permanently adopt other elements of its Hospital Without Walls services to ensure that these valuable services remain available to patients following the expiration of the COVID-19 public health emergency.

III. Incentive Payments for Domestically-Produced N95s

ASHP supports CMS's proposal to incentivize the purchase of domestically-produced N95s through a payment adjustment in both the hospital inpatient and outpatient settings. ASHP has long advocated initiatives designed to diversify supply chains and ensure that domestic sources of medication and supplies are maintained. We encourage the agency to adopt this approach as a means to safeguard the long-term supply of N95s.

Thank you for your consideration of our comments. We continue to support CMS's efforts to improve patient care and reduce patient costs, and we stand ready to assist the agency in any way possible. Please do not hesitate to contact me at 301-664-8698 or jschulte@ashp.org if ASHP can provide any further information or assist the agency in any way.

Sincerely,

Jillanne Schulte Wall

Jillanne Schulte Wall, J.D.
Senior Director, Health & Regulatory Policy