September 11, 2023

[Submitted electronically to www.regulations.gov]
Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1793-P
P.O. Box 8010
Baltimore, MD 21244-1850.

Re: Docket No. CMS-1793-P for "Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022."

Dear Administrator Brooks-LaSure:

ASHP is pleased to submit comments to the Centers for Medicare & Medicaid Services (CMS) regarding the proposed remedy for the 340B underpayment of 340B-eligible hospitals under the outpatient prospective payment system from 2018-2022. ASHP is the largest association of pharmacy professionals in the United States, representing 60,000 pharmacists, student pharmacists, and pharmacy technicians in all patient care settings, including hospitals, ambulatory clinics, and health-system community pharmacies. For over 80 years, ASHP has championed innovation in pharmacy practice, advanced education and professional development, and served as a steadfast advocate for members and patients.

ASHP thanks CMS for the opportunity to comment on the proposed rule. We urge the agency to consider our feedback as it refines and implements the repayment process for 340B underpayments. ASHP is generally supportive of the remedy structure outlined in the proposed rule, including a one-time lump sum payment administered by Medicare Administrative Contractors, the methodology for calculating the payments due, and the inclusion of the beneficiary cost-sharing amount in that calculation. We urge the agency to move forward with these elements of the proposed rule as soon as possible.

In order to ensure that providers are fully and fairly reimbursed for underpayments from 2018 – 2022, CMS must remove the cuts to payment for non-drug items and services and provide a method for providers to contest payment amounts from the MACs that do not match the hospitals' own calculations.

I. The 340B Underpayment Remedy Should Not Be Conditioned on Budget Neutrality.

We are strongly opposed to CMS's insistence on making the remedy budget neutral. There is simply no 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, recouping the payments for the non-drug items and services by cutting future payments does not negate the retrospective nature of the act. Stripping hospitals of reimbursement for services already rendered by cutting future payments 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. Given the questionable legality of the budget neutral element of the remedy, as well as the damage recouping these funds could do to hospitals and their patients, CMS should finalize the proposed rule without the cuts to non-drug items and services.

II. Hospitals Should Have A Method For Challenging Incorrect Payments

As noted above, ASHP strongly supports a remedy methodology that provides full and timely repayment to hospitals. We have no objection to the proposed repayment calculation methodology or the administration of the repayment by the MACs. However, miscalculations may occur, and the proposed rule does not outline a process for hospitals to challenge and/or remediate an incorrect amount provided by a MAC. Both hospitals and CMS have an interest in resolving any issue quickly, so we urge CMS to propose a quick, collaborative method for addressing any miscalculation of the remedy payments due. Specifically, the method should have clear, short timelines, without accountability for MACs to respond and resolve any issues quickly.

Thank you for your consideration of our comments. We urge CMS to move forward expeditiously with all elements of the proposed remedy, with the exception of the cut to non-drug items and services, which should be removed. 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