



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, DC 20201

Via electronic submission

**RE: Medicare Program; CMS–1793-P; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (RIN 0938-AV18) (July 11, 2023)**

Administrator Brooks-LaSure:

The Arkansas Hospital Association (AHA) is a membership organization that proudly represents more than one hundred health care facilities – and their more than 45,000 employees – as they strive to provide health care and community services for all Arkansans. On behalf of our member hospitals, I appreciate the opportunity to provide comments to the Department of Health and Human Services (HHS) regarding the proposed rule update (CMS-1793-P) to the Medicaid Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022.

We commend CMS for its decision to provide lump-sum payments to 340B participants who faced unlawful underpayments between January 1, 2018, and September 27, 2022. These payments will provide a necessary influx of funds that were lost by hospitals during the COVID-19 pandemic and due to the impact of inflation on health care costs, such as health care personnel, pharmaceuticals, therapeutics, medical supplies, and equipment in the last 50 years. Arkansas’s 340B-eligible hospitals use the program to not only ensure that patients have access to affordable medications but also to ensure access to essential care initiatives within our communities. These benefits of the 340B program provide hospitals with the opportunity to maintain essential care initiatives, while also serving as a buffer against the escalating impacts of inflation on staffing and vital medical supplies.

Nevertheless, we are disappointed in the proposed rule’s provisions to recoup funds from hospitals that did receive appropriate reimbursement between 2018 and 2022. Hospitals in Arkansas cannot afford additional cuts to their already insufficient reimbursement rates. The application of this proposed policy



will negatively impact the affected hospitals and will result in the inability to maintain services traditionally funded by the 340B program.

Not only are specific services in jeopardy, the decline in reimbursement rates – as stipulated by this proposed rule, coupled with an unprecedented inflation surge in staffing and medical services, insufficient reimbursement rates from Medicare and Medicaid, and the financial losses from fighting a once-in-a-century pandemic – presents the grim possibility of forcing the closure of our hospitals in our state. These institutions stand as crucial lifelines, caring for some of the most underserved populations within our rural communities.

For the reasons outlined above, and others described in subsequent paragraphs, we implore HHS to eliminate the provisions from the proposed rule associated with budget neutrality. We urge HHS to remedy these unlawful reimbursement practices *without* penalizing other hospitals that were lawfully reimbursed for services.

### **Finalize Proposed Remedial Payment**

The AHA fully supports the proposed rule described in CMS-1973-P that would require CMS to provide “one-time lump sum payments” to hospitals affected by CMS’s unlawful payment adjustments for 340B-acquired pharmaceuticals purchased between January 1, 2018, and September 27, 2022. Likewise, we support the use of HHS’s proposed payment methodology to calculate the repayment amounts, along with HHS’s proposal to compensate 340B hospitals the original reimbursements rates, had the unlawful 340B payment policy never come into effect.

In Arkansas, HHS is expected to disburse lump-sum payments to more than twenty-five 340B hospitals to rectify the unlawful underpayments between January 2018 and September 2022. Notably, the hospital payments range between a low of less than \$45.00 and a high of more than \$33 million, according to 340B redistribution calculations released by CMS. These funds are needed to continue to provide essential health care services to Arkansas’s hospital patients, and it is imperative that redistribution be seamless and expeditious.

Overall, the AHA is comfortable with the proposed mechanism to calculate the reimbursement repayments to hospitals. As described in the proposed rule, CMS calculates the proposed reimbursement amount using the “difference in payment for separately payable drugs at ASP minus 22.5% and SP plus 6% where the claim included the ‘JG’ modifier.” This methodology is intended to relieve some of the administrative burden for the recipient hospitals as well as for HHS personnel that are currently administering the Medicaid unwinding following the termination of the Public Health Emergency. It is imperative that any finalized methodology reduces the administrative workload, thereby ensuring that hospitals are not further burdened by the 340B repayment regulations.

Finally, the AHA appreciates HHS’s dedication to ensure that hospital repayment “comes as close to providing 340B covered entities with make-whole relief as CMS can reasonably accomplish.” In doing so,



HHS intends to process the 340B remedy repayments consistently with the manual processing of 340B claims, which rightfully ensures hospitals will receive reimbursement associated with beneficiary cost-sharing. By addressing the 340B underpayments and cost-sharing components, the proposed rule is an efficient way to fully composite 340B hospitals for the unlawful policies maintained by HHS from January 2018 through September 2022.

### **Do Not Finalize the Proposed Budget Neutrality Adjustment**

The AHA is deeply concerned about HHS's intent to pursue budget neutrality as a means to retroactively collect payments disbursed during a period when it unlawfully regulated the reimbursement of 340B pharmaceuticals. This concern aligns with the American Hospital Association's analysis, which asserts that HHS lacks the legal authorization or requirement to seek a "budget neutrality adjustment" for funds distributed during its unlawful operation of the 340B reimbursement program. This misinterpretation primarily stemmed from actions by the Health Resources and Services Administration (HRSA), and accountability should rest with HRSA and HHS, rather than burdening hospitals that had no choice but to accept HHS's proposed rates, regardless of accuracy.

The AHA vehemently opposes HHS's proposed mechanism to seek reimbursement from providers. The ramifications of such actions could disrupt essential health care services in Arkansas, particularly in rural areas, where access to care is already precarious due to inadequate reimbursement rates. It is crucial that HHS reevaluates its approach and considers the well-being of patients and the stability of health care facilities in the state.

While this proposed rule impacts traditional Medicare, most Medicare Advantage plans followed the reimbursement policies that have now been declared unlawful but have not been mandated to participate in the remedy. That means that Medicare Advantage plans have received an unjust windfall at the expense of 340B participating hospitals and patients who need hospital services. It is imperative that HHS consider the inclusion of Medicare Advantage plans in the budget neutrality adjustment process outlined in the rule. In fact, we urge HHS to consider a claw-back from the Medicare Advantage plans rather than from health care facilities that appropriately cared for patients.

If HHS insists on pursuing the budget neutrality adjustment, it should do so at a reduced rate consistent with the calculations proposed by the American Hospital Association in its comment letter on the topic. Additionally, the earliest HHS should initiate claw backs should be January 2026.

### **Conclusion**

While we commend HHS for its decision to provide lump-sum payments to 340B participants who faced unlawful underpayments during a critical period, we remain deeply concerned about the proposed budget neutrality adjustment. This adjustment threatens to have far-reaching and detrimental consequences on Arkansas hospitals as they strive to deliver essential services, especially in rural areas. We firmly believe that accountability for the reimbursement errors should rest with HHS and HRSA and



not be shouldered by the hospitals that have already been strained by the challenges of the past few years.

Furthermore, we appreciate the proposed remedial payment approach, which can provide much-needed relief to our hospitals following a period of financial uncertainty. We support the commitment to a fair and efficient reimbursement process, which considers the administrative burden on both hospitals and government personnel.

In conclusion, the AHA stands firmly in support of a fair and just resolution to the challenges faced by Arkansas hospitals. We urge HHS to carefully reconsider the proposed rule and prioritize the well-being of patients and the sustainability of health care facilities in our state. Our collective goal remains to ensure that all Arkansans have access to the health care services they need.

Thank you for your consideration of our comments.

Sincerely,



Bo Ryall  
President and CEO  
Arkansas Hospital Association

