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August 23, 2023

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 21244-8010

RE: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule (CMS-1793-P)

Dear Administrator Brooks-LaSure:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the proposed rule entitled “Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 Proposed Rule,” 88 *Fed. Reg.* 44078 (July 11, 2023), issued by the Centers for Medicare & Medicaid Services (CMS or the Agency).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, medical research, and community collaborations. Its members are all 157 U.S. medical schools accredited by the Liaison Committee on Medical Education; 13 accredited Canadian medical schools; approximately 400 teaching hospitals and health systems, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America’s medical schools and teaching hospitals and the millions of individuals across academic medicine, including more than 193,000 full-time faculty members, 96,000 medical students, 153,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Following a 2022 merger, the Alliance of Academic Health Centers and the Alliance of Academic Health Centers International broadened the AAMC’s U.S. membership and expanded its reach to international academic health centers.

The 340B Drug Pricing Program (340B Program) was created to allow certain safety-net hospitals and other providers (known as covered entities) that serve low-income, vulnerable patients to purchase covered outpatient drugs at a discount from drug manufacturers to help “stretch scarce Federal resources”¹ and expand services to these patients. Only hospitals that treat a significant share of vulnerable patients can qualify for the 340B Program. At no cost to taxpayers, the 340B Program allows safety-net providers to utilize the savings under the 340B Program to provide access to programs and services for their communities, including low-income, rural, and other underserved patients.

The savings generated by the 340B Program allow these often financially challenged providers to expand services to vulnerable populations, as the statute directs. In the decades of the 340B Program’s existence, the savings it produced have become essential to safety-net hospitals and other covered entities as they

¹ H.R. Rept. No. 102-384(II), at 12 (1992)

struggle to meet the needs of their communities and patients they serve. The 340B Program is an important program and must be safeguarded.

In the calendar year 2018 Outpatient Prospective Payment System (OPPS) final rule with comment² CMS finalized a policy to reduce reimbursement for drugs acquired under the 340B Program from average sales price plus 6 percent (ASP +6%) to average sales price minus 22.5 percent (ASP -22.5%).³ The reimbursement cuts began January 1, 2018.

This proposed rule outlines the litigation history related to these cuts (pp. 44079-44080). On June 15, 2022, the U.S. Supreme Court ruled⁴ that – absent a survey of hospital acquisition costs – CMS did not have the authority to reduce payments under the OPSS for 340B-acquired drugs and therefore would have to correct the underpayments hospitals received for 340B-acquired drugs. On September 28, 2022, the D.C. District Court ruled that CMS must begin reimbursing covered entities for 340B-acquired drugs immediately and not wait for a remedy to be finalized.⁵ The Court’s order vacated CMS’ policy prospectively for the remainder of 2022 but CMS allowed its Medicare Administrative Contractors (MACs) to apply the order for the entirety of 2022. The proposed rule offers a remedy to repay hospitals for the unlawful reimbursement cuts for drugs acquired under the 340B Program for the period between January 1, 2018, through September 27, 2022.

The AAMC strongly supports and asks CMS to finalize the proposal to issue one-time lump sum payments to hospitals to make up the difference between what they were paid (ASP -22.5%) and what they should have been paid (ASP +6%) for calendar years 2018 through 2021. In addition, we support the proposal that the lump sum payments would include beneficiaries’ coinsurance that would have been collected on the higher reimbursement that would have been in effect had the payment cuts not been in effect. We also agree with the agency’s methodology for calculating the repayments and agree that a lump sum payment minimizes burden for 340B hospitals and the agency. These portions of the rule should be finalized as soon as possible so hospitals and health systems can be repaid in 2023 for payments owed to them for calendar years 2018 through 2021. Claims reprocessing has already allowed hospitals to be repaid some amounts they are owed for calendar year 2022. We urge CMS to address 2022 through a mass adjustment for claims not already reprocessed with modifier “JG” on the claim that identifies payment was at the reduced rate for drugs acquired under the 340B program.

However, we oppose implementing the remedy in a budget neutral manner and urge CMS not to finalize this part of the proposal. The AAMC agrees with the American Hospital Association’s (AHA’s) comments⁶ that the agency does not have the legal authority to implement the remedy in a budget neutral manner. As the AHA explains, the agency cannot independently rely on its section 1833(t)(2)(e) of the Social Security Act “adjustment” authority under the prospective payment system or any common law authority to effectuate a retrospective “budget neutrality adjustment.” CMS lacks the legal authority to make the proposed \$7.8 billion “adjustment.” As the Supreme Court recently held in *Biden v. Nebraska*⁷, a statutory “adjustment” must be moderate or minor. But a \$7.8 billion retrospective claw back from all

² 82 FR 52356

³ Policy also impacts 340B-acquired drugs paid at wholesale acquisition costs (WAC) or average wholesale prices (AWP).

⁴ *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022)

⁵ *Am. Hospital Ass’n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 78 (September 28, 2022).

⁶ https://www.aha.org/lettercomment/2023-08-07-aha-letter-cms-remedy-340b-acquired-drug-payment-policy-calendar-years-2018-2022?utm_source=newsletter&utm_medium=email&utm_campaign=aha-today

⁷ No. 22-506, Slip Op. at 13 (June 30, 2023)

OPPS entities is anything but moderate or minor. It is likely that HHS did not have time to factor in this Supreme Court decision when issuing its proposed rule, but its final rule must account for it. The agency should not pursue any budget neutrality adjustment in the final rule.

LUMP SUM PAYMENTS

Publish an Updated Hospital-Specific Addendum with the Final Rule and Include Hospital-Specific Amounts Withheld During Calendar Year 2022

The proposed rule indicates that CMS expects most, if not all, of the claims for dates of services January 1, 2022, through September 27, 2022, would be reprocessed by the time the lump sum payments are issued, leaving mostly claims from CYs 2018 through 2021 reflected in the lump sum payment. The proposed rule further notes that the estimated amount for CY 2022 claims through September 27, 2022 – \$1.5 billion – may change by the time the final rule is issued. (p. 44084).

We ask that CMS include with the final rule an updated addendum of hospital-specific payments. Specifically, CMS should include a separate column in the Addendum AAA Excel file that shows the total amount withheld from each 340B hospital for the time frame, January 1, 2022, through September 27, 2022, before claims were reprocessed. This will allow hospitals to accurately calculate and confirm the CY 2022 reprocessed claims amounts. Further, we call on CMS to identify the data sets that it used, as well as the cut-off date for any claims data used, to calculate the amount of the reprocessed CY 2022 claims, even if these data sets are not publicly available.

Finalize the 60 Calendar Days' Time Frame to Require Medicare Administrative Contractors to Send Remedy Payments to Hospitals

CMS proposes to require the MACs to issue the lump sum payments to hospitals within 60 calendar days of the MAC's receipt of instructions from CMS. (p. 44085). The proposed rule states that due to the number of lump sum payments, the size of the payments, and the overall complexity of this remedy, 60 calendar days would provide the MACs with sufficient time to accurately and precisely make these payments. The AAMC supports this proposal and urges CMS to finalize it. Further, MACs should begin processing the lump sum payments as quickly as possible upon receipt of CMS' instructions; they should not wait the entire 60 days before issuing the repayments. CMS should require the MACs to submit to them weekly written updates on the status of the repayments.

PROSPECTIVE ADJUSTMENT TO OPPS PAYMENTS FOR NON-DRUG ITEMS AND SERVICES

As noted previously, the AAMC opposes CMS' proposal to implement the remedy in a budget neutral manner and asks CMS not to finalize any budget neutrality adjustments. Reducing reimbursement for non-drug items and services will further financially strain hospitals that continue to struggle with supply chain and workforce issues. Specifically, CMS proposes to prospectively reduce OPPS payments to hospitals for non-drug items and service by \$7.8 billion to maintain budget neutrality. (p. 44087). Beginning in CY 2025, CMS proposes to reduce all OPPS payments for non-drug items and services by reducing the OPPS conversion factor by 0.5 percent in future years until the total offset is reached. CMS estimates it would take approximately 16 years to recoup the entire amount. (p. 44087).

CMS does not appear to be applying budget-neutrality adjustments in a consistent manner in relation to 340B policies. The proposed rule states that "a budget neutrality adjustment is statutorily required, and

even if not statutorily required, warranted as a matter of sound public policy.” (p. 44081). Moreover, CMS notes that “budget neutrality in OPSS serves the important interest of limiting expenditures under Part B and thus protecting the public.” (p. 44081). This differs dramatically from what CMS has said and done in previous rulemaking. When stakeholders brought concerns to CMS about the need for budget neutrality calculations related to the 340B policy during previous rulemaking, specifically that the reimbursement decrease for 340B-acquired drugs was far greater than the increases in reimbursement for non-340B items and services, CMS did not see a need to update the budget neutrality adjustment as it had earlier committed to doing.⁸ However, in later rulemaking when public commenters repeatedly requested that CMS update the budget neutrality adjustment because it was apparent that spending on 340B-acquired drugs had increased, CMS declined to update the data used in the adjustment and insisted it was part of an overall budget neutrality adjustment and it would “not have a separate budget neutrality specifically for the 340B drug payment policy.”⁹ CMS *now* appears to believe that the remedy payments for the 340B payment policy require a budget neutral adjustment when it goes in its favor (p. 44081).

While AAMC disagrees that CMS must subject the additional 340B payments for the retrospective period to budget neutrality, we concur with the AHA’s recommendation that if the agency had the legal authority to pursue a “budget neutrality adjustment,” the agency should only be making a \$1.8 billion “adjustment” to correspond to the cost-sharing repayments the agency proposed. Further, CMS should not include CYs 2020-2022 in any “adjustment” because recouping funds that hospitals spent caring for patients during the COVID-19 public health emergency is not “equitable” under the statute.¹⁰ During this time frame, hospitals went above and beyond to care for patients and struggled financially. Any “additional” money hospitals received during that time from the adjustment to payments was spent to care for their patients and communities to address the additional challenges due to the COVID-19 public health emergency.

Annually Recalculate the Conversion Factor to Reflect the Budget Neutrality Impact of the 340B Policies

As noted above, AAMC and other commenters repeatedly asked CMS to update the budget neutrality adjustment in public comments on the OPSS rule after 2018 because utilization of 340B-acquired drugs increased, making the reductions in payment for the 340B drug policy higher. This necessitated an increase to the original budget neutrality adjustment CMS initially made in 2018. While CMS declined to make the adjustment, CMS acknowledges the validity of this point in the proposed rule -- “...we now know our estimate of the reduction in expenditures for 340B drugs was lower than the actual amount by which expenditures for 340B drugs were reduced in CYs 2018 through 2022. Therefore, our budget neutrality calculations for those years ended up increasing payments for non-drug services by less than we decreased payments for 340B drugs.” (p. 44088).

Given this experience, we urge CMS to provide greater transparency of its calculations by including the budget neutrality calculations related to the recoupment in each future year’s OPSS proposed rules. This proposed rule does not provide sufficient information on the impact of the decreased conversion factor on individual hospitals. The proposed rule notes that CMS cannot adequately estimate how long the

⁸ See 82 FR 59483 where CMS stated “As a result, we may need to make an adjustment in future years to revise the conversion factor once we have received more accurate data on drugs purchased with a 340B discount within the OPSS.

⁹ 86 FR 63648

¹⁰ https://www.aha.org/lettercomment/2023-08-07-aha-letter-cms-remedy-340b-acquired-drug-payment-policy-calendar-years-2018-2022?utm_source=newsletter&utm_medium=email&utm_campaign=aha-today

recoupment process will take; therefore, we request that CMS annually report on the amount of money recouped each year because of the conversion factor decrease.

Publicly Report on an Annual Basis the Calculations and the Total Recoupment Amount

The proposed rule estimates that it will take approximately 16 years to offset the \$7.8 billion for the increased payments for non-drug items and services. (p. 44087). If CMS moves forward with its budget neutrality adjustment, the AAMC calls on CMS to provide greater clarity on individual hospital's repayment obligations during the recoupment period. Changes in utilization could make the estimated recoupment period longer or shorter than CMS estimates. It could further result in hospitals refunding more in additional payments than they ever received during the CY 2018 through CY 2022 period. CMS should ensure that hospitals not be required to pay more in the recoupment than what they were initially paid during the time frame.

There are other factors that could impact the recoupment that CMS should address in the final rule. For example, how will hospital closures impact the recoupment? Hospitals continue to face financial struggles in the aftermath of the COVID-19 public health emergency that brought unprecedented supply chain and workforce challenges. Some hospitals were not able to withstand the financial pressures and closed; almost 100 hospitals since 2019.¹¹ If more hospitals close during the recoupment period which would span decades, how will these closures impact other hospitals repayment obligations during the recoupment period? Will hospitals that remain open be required to shoulder the debt associated with the closed hospitals? Such a policy would be highly unfair. A given hospital should not be required to refund more in additional payments than it ever received merely because another hospital is no longer able to pay its share.; solely because of an unlawful CMS .

Further, how will recoupment be affected as more beneficiaries choose to enroll in a Medicare Advantage plan? According to KFF, just over half of eligible Medicare beneficiaries are enrolled in a Medicare Advantage (MA) plan.¹² A decrease in beneficiaries enrolled in traditional Medicare will shrink the pool upon which the recoupment is based. Utilization under traditional Medicare will decline as more beneficiaries opt to have their Medicare benefits administered by a Medicare Advantage plan. The decline in traditional Medicare enrollment will directly impact recoupment. How will CMS account for the recoupment if enrollment in MA plans continues to rise? Will the recoupment burden be assessed on a smaller base of services (e.g., requiring either a higher proportional reduction or longer payback period?) Again, this would be a highly unfair policy and would require a hospital to refund a larger percentage of their fee-for-service payments or stretch out the refund period for circumstances beyond its control. for a policy that was unlawfully adopted by CMS.

Potential Decrease in Future MA Payments to Hospitals

MA plans pay hospitals based on traditional Medicare rates. Decreasing the conversion factor would likely result in reduce MA reimbursements hospitals receive over the anticipated 16-year recoupment time frame. Decreased reimbursement from MA plans would double the adverse impact of the proposed

¹¹ Medicare Payment Advisory Commission. Hospital inpatient and outpatient services. Chapter 3. March 2023 Report to Congress. https://www.medpac.gov/wp-content/uploads/2023/03/Ch3_Mar23_MedPAC_Report_To_Congress_SEC.pdf

¹² <https://www.kff.org/policy-watch/half-of-all-eligible-medicare-beneficiaries-are-now-enrolled-in-private-medicare-advantage-plans/>

recoupment on hospitals and potentially jeopardizing access to care for some beneficiaries. The problem will compound throughout the 16 years as more beneficiaries choose to enroll in MA plans.

Delay Implementation of the Decrease in the Conversion Factor Until CY 2026

CMS should delay the implementation of the decrease in the conversion factor until CY 2026 if it chooses to finalize this proposal. Hospitals still face financial challenges from the COVID-19 public health emergency, with margins, a single indicator of financial strength, below historical norms. Medicare reimbursement is already inadequate. Medicare pays hospitals, on average, 84 cents for every dollar of care provided.¹³ AAMC-member teaching hospitals overall Medicare margins are negative 18.8 percent in fiscal year 2020.¹⁴ Implementing these cuts as hospitals attempt to regain their financial footing will undermine their chances of success and could push some hospitals to close. Therefore, CMS should delay implementation if it chooses to finalize this proposal.

MEDICARE ADVANTAGE PAYMENTS FOR 340B-ACQUIRED DRUGS

Many MA plans also reduced reimbursement for 340B-acquired drugs during the time frame the OPPI payments were reduced. While this may be outside the scope of this proposed rule, we call upon CMS to take all possible measures within its authority to ensure MA plans comply with the remedy and provide hospitals with the legally-required repayments. MA plans refusal to pay the difference between the unlawful 340B policy amounts and what hospitals are owed would be a windfall to MA plans which goes against the goal of lessening the impact of CMS' past mistakes on the Part B Trust Fund.

CONCLUSION

Thank you for the opportunity to comment on this proposed rule. We would be happy to work with CMS on any of the issues discussed or other topics that involve the academic community. If you have questions regarding our comments, please feel free to contact Mary Mullaney at mmullaney@aamc.org.

Sincerely,



Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P.
Chief Health Care Officer

cc: David Skorton, M.D., AAMC President and Chief Executive Officer

¹³ <https://www.aha.org/news/opinion-editorial/2023-07-07-proposed-medicare-cuts-jeopardize-access-care-patients-and-communities#:~:text=The%20reality%20is%20Medicare%20severely,for%20Medicare%20patients%20in%202020>.

¹⁴ <https://www.aamc.org/media/10266/download?attachment>