Illinois Health and Hospital Association

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, D.C. 20201

Re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (CMS1793-P)

Dear Administrator Brooks-LaSure:

On behalf of our over 200 hospitals and nearly 40 health systems, the Illinois Health and Hospital Association (IHA) appreciates the opportunity to comment on the U.S. Dept. of Health and Human Services' (HHS) proposed remedy following the Supreme Court's decision in American Hospital Association v. Becerra, 142 S. Ct. 1896 (2022).

Overall, IHA strongly supports several provisions of the proposed remedy, and we urge HHS to finalize these provisions as soon as possible. We applaud the agency's proposal for a one-time lump sum repayment to hospitals for underpayments experienced from calendar years (CY) 2018 through 2022 when purchasing 340Bacquired outpatient drugs. We also strongly support the agency's decision to repay what hospitals would have received in beneficiary cost sharing. Further, we agree with HHS' proposed methodology for calculating this lump sum payment, inclusive of forgone beneficiary cost sharing.

However, IHA continues to disagree with the agency's proposal to use retrospective clawbacks of funds that hospitals received because of illegal Medicare cuts made between CYs 2018 through 2022 to maintain budget-neutrality for this lump sum payment. The Centers for Medicare & Medicaid Services (CMS) should forgo such a measure as we disagree with the agency's interpretation of the statute and do not believe HHS has the authority to utilize retrospective clawbacks to maintain budget-neutrality. While we appreciate HHS' proposal to lessen the burden of its proposal by spreading it out over 16 years and delaying the recoupment start date, the agency is still pursuing an aggressive amount of money that we do not believe it can retrospectively clawback under inapplicable budget-neutrality provisions. Therefore, we urge the agency to forgo the clawback altogether and use its acquiescence authority to repay 340B hospitals.

Again, thank you for the opportunity to comment on this proposed remedy. We look forward to working with HHS to ensure the 340B program continues to fulfil its intent, which is to provide 340B hospitals and the vulnerable communities they serve with the resources to improve the health and well-being of their patients. Our detailed comments are below.

Proposed Lump Sum Repayment

IHA fully supports the proposed remedy to provide 340B hospitals with a lump sum payment, correcting HHS' illegal underpayments for 340B-acquired drugs through CYs 2018 through 2022. We believe this proposed remedy is appropriate and responsive to the Supreme Court's decision that HHS' prior payment policy of average sales price (ASP) minus 22.5% was unlawful, and that a lump sum payment complies with the unanimous decision that HHS must apply the default rate of ASP plus

6%.

According to CMS' calculations, Illinois 340B hospitals will receive an estimated $334.8 million to correct for underpayments made between CYs 2018 and 2022. Our 340B hospitals, including Safety Net Hospitals and Critical Access Hospitals, serve some of Illinois' most vulnerable communities. The absence of these funds, particularly during an unprecedented pandemic that severely depleted hospital funds, was challenging and our hospitals continue to build back as they face workforce challenges, steep inflation, and rising costs.

We also applaud the agency's initiative to repay hospitals for forgone beneficiary cost-sharing amounts. Doing so is the best and most fair way for HHS to fully compensate 340B hospitals for this unlawful payment policy. Making 340B hospitals fiscally whole under this program is undoubtedly the correct course of action particularly given the intent of both the 340B and Medicare programs.

In addition, we appreciate the agency's decision not to pursue forgone beneficiary cost-sharing amounts from patients themselves. We agree with HHS' stance that if the agency did not make these repayments itself, "beneficiaries could be caught by surprise by a significant change in cost-sharing responsibility from a claim they thought had been closed many years ago." Patients do not deserve such a "surprise," and the agency should not force hospitals and health systems to demand that their patients pay for HHS' mistakes. Thus, we fully support HHS' proposal to cover the cost-sharing portion of the underpayment to prevent these consequences and protect both 340B hospitals and the patients they serve.

Finally, we appreciate HHS' approach to calculating these underpayments. Specifically, by not requiring the reprocessing of past claims, HHS is relieving a large burden on hospitals, health systems, CMS, and Medicare Administrative Contractors.

IHA supports the above proposals made by HHS and urge the agency to finalize these proposals as quickly as possible. Doing so will bolster the ability of 340B hospitals to provide vital healthcare services to their patients and the historically underserved communities they serve.

HHS' Proposed Budget Neutrality Adjustment

While IHA appreciates HHS' commitment to respond appropriately to the Supreme Court decision and provide 340B hospitals with a lump sum repayment, we strongly disagree that HHS must make lump sum payments in a budget neutral way. HHS' attempt to mitigate the impact of its budget neutral adjustment proposal by decreasing the OPPS payment rate by 0.5% over approximately 16 years notwithstanding we maintain that this retrospective clawback is neither statutorily required nor permitted.

We believe HHS has inappropriately interpreted the OPPS statute. Specifically, a plain reading of sections 1833(t)(9)(B) and 1833(t)(14)(H) of the Social Security Act does not require (nor permit) HHS to make budget neutrality adjustments for past payments. It clearly states budget neutrality is made prospectively. Budget neutrality is required for future payments and is meant to adjust the groups, relative payment rates, and wage indices in the OPPS for the upcoming year, taking into account changes in services, changes in technology, new cost data, etc.—not payments that have already been made.

Instead of creating policy based on the misguided reading of the statute, HHS should use its acquiescence authority to repay 340B hospitals. This approach has been used in the past (see e.g., *Grant Medical Center v. Hargan*, 875 F.3d 701 (D.C. Cir. 2017) and *Johnson v. U.S. R.R. Retirement Bd.*, 969 F.2d 1082 (D.C. Cir. 1992)). In this case, the Supreme Court unanimously held that the agency must pay 340B hospitals the ASP plus 6% rate. HHS can simply acquiesce in that holding and repay accordingly. In fact, HHS already utilized such authority to provide some remedial payments for 340B drug claims with dates of service between Jan. 1, 2022 and Sept. 27, 2022. Thus, it stands to reason that HHS would be within its rights to continue following
that logic in repaying additional 340B claims from CYs 2018 through 2022.

We strongly urge HHS to rely on precedent, particularly within its own repayment of 340B claims, and forgo any budget neutrality adjustment via this payment remedy. OPPS hospitals have already spent payments made between CYs 2018 and 2022, and clawing back these funds will be financially burdensome to hospitals. Illinois hospitals currently have an outpatient Medicare margin of approximately -17%. Any cut to payments, even a small one, will further exacerbate the financial strain

hospitals continue to face under a system that does not cover the cost of care.

In conclusion, IHA is pleased that lawful payment rates for 340B-acquired drugs have been restored. IHA applauds HHS' commitment to repaying 340B hospitals in full, inclusive of beneficiary cost-sharing. We also appreciate the simple and streamlined approach HHS has taken in calculating the lump sum payments it will make to 340B hospitals. We continue to object to HHS' stance that it must make a budget neutral adjustment to offset this lump sum payment, as we believe this is a misinterpretation of the OPPS statute and there is legal
standing for HHS to rectify underpayments without any such adjustments.

Thank you for your consideration of these issues.

Sincerely,

A.J. Wilhelmi
President & CEO
Illinois Health and Hospital Association

Your trusted voice and resource

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