ALLIANCE of SAFETY-NET HOSPITALS

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Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-1850

Subject: 42 CFR Part 419 [CMS–1793–P], RIN 0938–AV18 Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022

Attention: File Code CMS-1793-P

To Whom it May Concern:

I am writing on behalf of the *Alliance of Safety-Net Hospitals,* a group of private community safety-net hospitals that serve economically disadvantaged and underserved communities, to convey to the Centers for Medicare & Medicaid Services (CMS) our views on its proposed remedy for a past reduction in 340B program reimbursement that was invalidated by the Supreme Court earlier this year. This proposed remedy was published in the *Federal Register* on July 11, 2023 (Vol. 88, No. 131, pp. 44078-44096).

All Alliance of Safety-Net Hospitals (ASH) members currently participate in the 340B program, and with this in mind, we would like to convey our general support for much of what CMS has proposed while expressing our objections to selected parts of its proposal.

ASH Supports CMS's Proposal for Reimbursing 340B Participants for Lost Payments – With Some Qualifications

ASH greatly appreciates the centerpiece of CMS's proposed remedy for the invalidated multi-year reduction of 340B payments to eligible providers: making single lump-sum payments that compensate those providers for their lost revenue during the period in which the payments were reduced. We look forward to

receiving these payments and hope we will do so before the end of calendar year 2023 – shortly after this regulation is finalized; it is essential that community safety-net hospitals be reimbursed for the payments we were due in as timely a manner as possible. The proposal to make one-time lump sum payments is undoubtedly the best remedial approach, minimizing burden for 340B hospitals and the agency. We also support CMS's plan to pay 340B providers what they would have received from beneficiary cost-sharing had the overturned 340B policy not been in effect.

Contrary to the proposed remedy, however, ASH believes CMS should pay 340B providers interest on the long-delayed payments. The Medicare Claims Processing Manual (Pub, 100-04, Chapter 1, Section 80.2.2) provides instructions for assessing and calculating interest due on non-periodic interim payment (PIP) claims not paid in a timely manner by fiscal intermediaries (FIs) and carriers. It states that interest must be paid for clean claims not paid within 30 days after the day of the receipt of a claim and that interest accrues until and including the day of late payment.

We believe providers are due interest for these payment shortfalls and disagree with CMS's assertion, as stated in the proposed regulation, that it lacks the authority to pay this interest.

In addition, while we support the general methodology CMS says it has employed to calculate the proposed payments, we ask the agency to share with participating 340B providers more details about this methodology and a list of their 340B claims on which it was used.

As noted, because of the significant challenges community safety-net hospitals face and the significant amount of money we lost because of 340B underpayments, ASH encourages CMS to make these lump-sum payments as quickly as possible and urges CMS to finalize this section of the rule.

Finally, we ask CMS to establish a process through which 340B providers can appeal the agency's calculation of their remedy payment after the lump-sum payments have been made. Issues can arise with the data reported, the data used, and the calculations themselves, and we believe hospitals should have an opportunity to review the calculations for themselves and appeal the remedy amount, should such a need arise.

ASH Opposes CMS's Recoupment Proposal

ASH strongly opposes CMS's proposal to implement future Medicare payment cuts so the agency can recoup the additional payments it must make to 340B providers in the wake of the Supreme Court decision. While we appreciate the kind sentiment underlying the proposal to extend recoupment through a period of 16 years, we believe proposing recoupment in any form is utterly counter-intuitive and not required by the Supreme Court decision. It also could be especially harmful to community safety-net hospitals that already operate on razor-thin margins.

The basis of this recoupment plan is CMS's assertion that it must, or that it may, make the remedy payments in a budget-neutral manner. We do not believe it has the option to do either. Contrary to the arguments

the agency advances to support its recoupment proposal, we believe neither position is justified and that the statute on which CMS relies for proposing this recoupment neither requires budget neutrality nor authorizes a recoupment effort. Instead, CMS has chosen to do this of its own volition even though it is under no compulsion to do so.

The arguments CMS makes in favor of budget neutrality do not hold up to closer scrutiny:

- The portion of the Social Security Act cited in the proposed rule does not support pursuing budget neutrality.
- In a recent case, the Supreme Court ruled that "adjustments" – and CMS is calling this a "budget-neutrality adjustment" – may seek only "to change moderately or in a minor fashion." In our view, a $7.8 billion "adjustment" is in no way minor or moderate, suggesting that this aspect of the proposed remedy is contrary to case law that has been reaffirmed as recently as earlier this summer in the case of *Biden v. Nebraska*.
- Justifying such an adjustment as a response to the "windfall" 340B participants will be receiving through the proposed repayment is completely inappropriate inasmuch as the only reason providers will be receiving these payments at all is Medicare's illegal reduction of their past payments. They are compensation for a past injustice and should not be labeled in a manner that implies that they are somehow undeserved.

For these reasons, ASH urges CMS to withdraw its proposal to seek to recoup the $7.8 billion at the expense of providers that care for Medicare patients.

In the proposed rule CMS asks stakeholders if it should delay the start of the recoupment. ASH believes that if CMS decides it must recoup this money, CMS should refrain from starting this recoupment until 2026 out of consideration for the extraordinary financial challenges hospitals currently face: the lingering effects of COVID-19; inflation; the rising cost and declining availability of qualified health care professionals; eroding margins; and the significant loss of Medicaid coverage we expect so many of our patients to suffer in the coming months, leaving them without health insurance – and leaving providers with a new uncompensated care challenge. The COVID-19 emergency proved especially challenging to community safety-net hospitals, which serve far more low-income, uninsured, and under-insured patients than the typical hospital and often found themselves without the financial strength that other hospitals enjoyed to invest in the resources, both human and material, required to respond to that crisis. The post-pandemic years promise to be no less challenging in some respects as these hospitals now face the prospect of many of their patients losing their Medicaid coverage.

Finally, if CMS insists on pursuing recoupment, $7.8 billion is too much to seek to recover. ASH believes the $7.8 billion figure should be reduced both to correspond only to the size of the $1.8 billion in proposed cost-sharing adjustments and to exclude calendar years 2020 through 2022, when hospitals were on the front lines of a once-in-a-century pandemic that caused profound financial harm to them that continues today.

Medicare Advantage, Unpaid 340B Claims, and the Future Effects of Recoupment

ASH urges CMS to ensure that Medicare Advantage organizations comply with this remedy in the same manner that Medicare does. Late last year CMS reminded these plans that in the wake of the court decision overturning the 340B payment cut they must repay the 340B providers with which they work to compensate those providers for the same 340B payment shortfall. Our experience suggests that some Medicare Advantage organizations have not complied with this reminder and have not compensated 340B providers for their past payment shortfalls. ASH urges CMS to take steps to ensure that Medicare Advantage organizations comply with the same judicial requirement as the agency is now seeking to do through this proposed rule. To do otherwise would be to permit non-complying Medicare Advantage plans to reap a windfall of revenue they did not earn – at the expense of the providers serving their members.

ASH also believes CMS must account for the Medicare Advantage organization windfall that will result from the proposed -0.5 percent adjustment to payment rates, especially if the Medicare Advantage organizations continue to refuse to pay the difference between the unlawful 340B policy amounts and what hospitals are owed**.** This windfall to Medicare Advantage organizations does not advance CMS's stated primary public policy objective: lessening the impact of HHS's past mistakes on the SMI Trust Fund. With more than half of Medicare beneficiaries enrolled in a Medicare Advantage plan, the potential scale of the recoupment from hospitals could potentially double but would only serve to pad Medicare Advantage organizations' skyrocketing profits.

Conclusion

ASH appreciates the overall manner in which CMS has proposed addressing this challenge, and in particular, its expressed desire to make prompt and full reimbursement payments to 340B providers for the losses they suffered from the policy rejected by the Supreme Court. As community safety-net hospitals, our members serve especially large numbers of 340B patients and therefore have been especially harmed by three years of 340B underpayments. We believe our suggested refinements would approve the remedy CMS has proposed and make it fairer for all concerned – including the low-income patients the 340B program was created to serve and the dedicated providers that consistently step forward in communities across America to serve them. We welcome any questions you may have about the views expressed in this letter.

Sincerely,

Ellen Kugler, Esq.
Executive Director

About the Alliance of Safety-Net Hospitals

The Alliance of Safety-Net Hospitals is a coalition of like-minded community safety-net hospitals without dedicated sources of public funding that work together to advocate policy decisions on government health care programs, most notably Medicare and Medicaid, that ensure equitable access to care for the medically vulnerable residents of the communities they serve and adequate public resources for the safety-net hospitals that serve those communities.