A Passionate Voice for Compassionate Care

September 5, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Room 445-G Herbert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

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

Dear Administrator LaSure:

The Catholic Health Association of the United States (CHA) is pleased to submit these comments on the Centers for Medicare & Medicaid Services' (CMS) proposed Remedy for the 340B-Acquired Drug Payment Policy in the Hospital Outpatient Prospective Payment System for Calendar Years 2018–2022 (88 Fed. Reg. 44078, July 11, 2023).

Beginning in 2018, CMS adopted a policy to pay for drugs and biologicals acquired under the 340B program at average sales price (ASP)-22.5% rather than ASP+6%, the rate for separately payable drugs under the OPPS. The United States Supreme Court rejected that policy in *American Hospital Association v. Becerra,* 142 S. Ct. 1896 (2022) as contrary to the Medicare statute. **CHA is pleased CMS has now proposed providing a one-time lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B program for CY 2018-2022 and we strongly support this.** CHA is also supportive of the proposed methodology for calculating the 340B repayments. We also endorse the proposal to include the additional amount that hospitals would have received in beneficiary cost-sharing. CHA urges CMS to finalize these policies as proposed.

However, CHA is strongly opposed to the proposal to apply budget neutrality to offset the legally required repayment plan. We question CMS' assertion that it has a statutory obligation to proceed with the remedy in a budget-neutral manner and believe that CMS has both the legal flexibility and legal obligation to refrain from recouping funds paid to hospitals due to its own mistaken policy. **CHA urges CMS not to finalize the proposal to apply a "budget neutrality adjustment."**

1875 Eye Street NW, Ste. 1000 Washington, DC 20006 *phone* 202.296.3993 *fax* 202.296.3997 **www.chausa.org**

Repayment of Withheld 340B Payments

CMS considered and rejected manually processing claims at a rate of ASP+6 percent for the covered period. Instead, it proposes to make a one-time lump sum payment to each 340B hospital. which it believes will come as reasonably close as possible to making hospitals whole while avoiding the massive administrative burden of reprocessing claims. To determine the amount due to 340B hospitals, CMS would calculate the difference between what was paid for 340B drugs, ASP-22.5%, during the relevant time period and the rate that should have been paid, ASP+6%. **CHA supports making one lump sum payment based on this method to repay 340B hospitals.**

The 340B discount drug program plays a critical role in allowing safety net and rural hospitals to continue to meet the needs of their patients and communities. As CMS has acknowledged in past rulemaking, the program is intended to "maximize scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." (82 Fed. Reg. 33558, 33632, July 20, 2017). Savings from the 340B program allow CHA members, for example, to run free and low-cost clinics; to provide services in remote or low-income areas; offer generous financial aid policies; provide low-cost or free prescriptions; maintain critical services that operate at a loss; and support community programs meeting the identified needs of their service areas.

As a result, 340B Disproportionate Share Hospitals (DSHs) continue to serve a greater share of patients with low incomes and from marginalized communities. A 2022 study concluded that "340B hospitals continue to treat a higher proportion of patients with demographic and other characteristics associated with medical complexity and greater challenges related to access to appropriate, quality care … provid[ing] care for a larger proportion of Medicare beneficiaries who are disabled, are dual-eligible, and/or identify as part of racial or ethnic minority communities compared to non-340B hospital and office-based providers."[1]

Being denied full reimbursement for 340B drugs posed significant challenges for 340B hospitals. Providing the proposed lump-sum repayment as soon as possible will have an enormously positive impact on these hospitals and the communities they serve. CMS proposes to instruct the Medicare Administrative Contractors to issue the one-time lump sum payment within 60 calendar days. **CHA supports reimbursing 340B hospitals in the fastest manner possible.** We urge CMS to ensure it happens in no fewer than 60 days. If the MACs indicate processing can occur more quickly, CMS should finalize that shorter time period. Hospitals should receive their repayments before the end of the current calendar year.

Beneficiary Cost Sharing

---

[1] L&M Policy Research. Examination of Medicare Patient Demographic Characteristics for 340B and Non-340B Hospitals and Physician Offices. July 2022, available at ***https://www.340bhealth.org/files/LM-340B-Health-Demographic-Report-07-28-2022_FINAL.pdf***

CMS proposes to include in the lump-sum payment the amount 340B hospitals would have received in beneficiary cost-sharing had they been paid properly during 2018-2022, and to instruct hospitals that they may not bill beneficiaries for coinsurance on remedy payments. **CHA strongly supports the proposals concerning beneficiary cost sharing.** Hospitals must receive these amounts to be made whole, but patients must also be protected from having to pay for costs for care that occurred years ago and was, so they thought, closed. CMS' inclusion of cost-sharing amounts in the repayment spares patients from unexpected costs and gets closer to making hospitals whole.

Proposed Budget Neutrality Adjustment

CMS proposes to rely on sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act for its authority to make the remedial payments. These statutes, as CMS notes, require OPPS payment adjustments to be done in a budget-neutral manner. However, CMS does not assert it is *required* to rely on these statutes when meeting its court-ordered obligations but rather it is *choosing* to do so in order to remedy its error. In the proposed rule, CMS states that it "believe(s) we would have the authority to make remedy under sections 1833(t)(2)(E) and 1833(t)(14) of the Act, along with our retroactive rulemaking authority in section 1871(e)(1)(A) of the Act." The agency also notes that "sections 1833(t)(2)(E) and 1833(t)(14) of the Act require budget neutrality with respect to payment adjustments to the OPPS made under those sections and are not specific to remedy payments." (88 Fed. Reg. 44078, 44080). Having made the *choice* to rely on sections 1833(t)(2)(E) and 1833(t)(14), CMS throughout the preamble asserts that it is statutorily required to pursue budget neutrality. But that "requirement" rests not on the demands of the statute but the choice of CMS. **CMS can and should make the remedial payments not under the auspices of the statute but in compliance with the order of the Supreme Court and should not apply budget neutrality to the remedial repayments.** CMS should rely on acquiescence to the Supreme Court's ruling for making the payments, as it has in processing remedial payments for the period January 1, 2022 through September 27, 2022. Indeed, the Supreme Court's June 2022 decision only applied to CYs 2018 and 2019, making the acquiescence even more noteworthy.[2]

We also question whether those two statutes do indeed give CMS authority to apply budget neutrality. Section 1833 (t)(14)(H) addresses additional expenditures under the paragraph, but the remedial payments result not from the operation of that paragraph but from the Supreme Court's unanimous decision invalidating the agency's position. Furthermore, the payments are not "additional" but are instead amounts 340B hospitals should have been paid in the first place. Finally, section 1833(t)(14)(H) expressly incorporates "paragraph (9)," which makes clear that budget neutrality is a prospective exercise that directs CMS to annually adjust the groups, relative payment weights, and wage indices in the OPPS for the upcoming year, taking into account changes in services, changes in technology, new cost data, and the like. See 42 U.S.C. § 1395l(t)(9)(A).

[2] In its comment letter on the proposed remedy, the American Hospital Association lays out in further detail the argument for acquiescence, including references to several occasions when CMS has acquiesced to judicial rulings by entering settlements with hospitals rather than issuing new regulations.

These *prospective* changes must be budget-neutral, which only means that they cannot cause any change in "the estimated amount of expenditures ... for the year." Id. § 1395l(t)(9)(B) (emphasis added). The plain text of paragraph (9), therefore, does not address past years or retrospective recoupments.

Turning to section 1833(t)(2)(E), that provision gives the HHS Secretary authority to make "other adjustments as determined to be necessary to ensure equitable payments" and must do so in a budget-neutral manner. In other words, the Secretary can make discretionary payments for equitable reasons. But the Secretary is making these payments because the Supreme Court held the prior policy illegal, not through his discretion for equitable reasons. The authority established under this section is not relevant to the remedial payments; therefore, its budget neutrality requirement does not apply.

In the preamble, CMS asserts it is required to maintain budget neutrality "[t]o the extent that" the remedial payments "are understood as" an 1833(t)(2)(E) payment adjustment or "to the extent that" they "are understood as" a section 1833(t)(14) payment. As discussed, neither section of the statute aptly applies to the remedial payments. Furthermore, the fact that CMS has couched its action in conditional language rather than making a straightforward assertion of law further supports the conclusion that CMS has made a choice to use these statutes.

CMS' policy justifications also do not support a "budget neutrality adjustment." The agency's repeated reference to a "windfall" completely ignores its own role in creating this situation. When the agency implemented its unlawful policy and continued to defend it for many years, hospitals had no choice but to accept these funds. These hospitals should not be adversely impacted in the future by the agency's own unlawful past actions. In addition, clawing back the distributed 340B payments would further exacerbate the financial challenges already faced by hospitals and health systems. Hospitals are still feeling the financial effects of COVID-19, on top of Medicare's systemically inadequate reimbursement and the rising costs they face.

CHA strongly urges CMS not to apply budget neutrality to the repayment of wrongfully withheld 340B reimbursements. Given CMS's position, we appreciate the effort to mitigate the impact by proposing a prospective 16-year offset period with a delayed start. If CMS does finalize its intent to make the repayments budget-neutral, we urge the agency to finalize the recoupment plan as proposed. We would also ask CMS to seek ways to lower the amount it recovers below the proposed $7.8 billion.

Medicare Advantage Organizations (MAOs)

CHA is concerned that MAOs have not been repaying hospitals what they are owed for past 340B underpayments. MAO plans have been unjustly enriched by following CMS's unlawful policy for CYs 2018-2022 and are obligated to repay hospitals for the payment cuts they made based on the illegal OPPS payment rate. While this issue may not be within the scope of the proposed rule**, we**

urge CMS to take all possible measures within its authority to ensure MAOs comply with the remedy so that they do not receive an inadvertent windfall. We also ask that CMS account for the MAO windfall that will result from the proposed -0.5% adjustment to payment rates, especially if the MAOs continue to refuse to pay the difference between the unlawful 340B policy amounts and what hospitals are owed. The complications associated with this windfall provide yet another reason why CMS should not pursue a budget-neutral adjustment. **Should CMS choose to finalize such an adjustment, we urge the agency to craft a recoupment that addresses this MAO double-dipping problem**. Whether it is lowering the overall "adjustment" amount to account for the MAO windfall or finding another way to recoup funds that address it (e.g., through a cost report reconciliation rather than through the payment rate or PRICER), the issue should be addressed in the final rule.

In closing, **CHA thanks CMS for proposing a one-time lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B program for CY 2018-2022 and urges finalization of the proposal. However, we strongly oppose making the repayment in a budget-neutral manner**. Thank you for the opportunity to share these comments on the proposed 340B remedy. We look forward to working with you on these and other issues that continue to challenge and strengthen the nation's hospitals. If you have any questions about these comments or need more information, please do not hesitate to contact me or Kathy Curran, Senior Director, Public Policy, at 202-721-6300.

Sincerely,

Lisa A. Smith
Vice President
Advocacy and Public Policy