September 11, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Ave., S.W.
Washington, D.C. 20201

SUBJECT: (CMS-1793-P) Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022; Federal Register (Vol. 88, No. 131), July 11, 2023

Dear Administrator Brooks-LaSure:

On behalf of our more than 400 member hospitals and health systems, including many 340B-covered entities, the California Hospital Association (CHA) is pleased to submit comments on the Centers for Medicare & Medicaid Services' proposed remedy related to the adjustment of Medicare payments for drugs acquired under the 340B drug pricing program for calendar years (CY) 2018-2022 (hereafter "340B remedy").

California's hospitals are struggling financially because of inadequate governmental payment rates and rapidly increasing costs — particularly for clinical labor. The financial pressure that continues to build is such that nationally renowned consulting firm Kaufman Hall estimates[1] that one in five California hospitals are at risk of closure. As evidence of this pressure, so far in 2023, one California 340B hospital (Madera Community Hospital) has closed and another (Beverly Hospital) has declared bankruptcy. Even more concerning, many other 340B hospitals are in severe financial distress and perilously close to reducing services, declaring bankruptcy, or shuttering outright. This severe financial distress has been exacerbated by the unwarranted reduction in 340B payments and the continued delay in correctly paying participating hospitals after the Supreme Court ruling in June 2022.

Research by the National Bureau of Economic Research shows[2] that hospital closures — particularly rural closures — increase inpatient mortality by 8.7%, with Medicaid patients and racial minorities bearing the brunt of negative outcomes — 11.3% and 12.6% increases in mortality, respectively. These are people's

[1] https://www.kaufmanhall.com/sites/default/files/2023-04/CHA-Financial-Impact-Report.pdf
[2] https://www.nber.org/system/files/working_papers/w26182/w26182.pdf

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lives, not abstract data points. Sadly, at least two individuals' deaths have already been attributed to Madera Community Hospital's closing.[3]

Further, a recent survey by the Jakara Movement and Centro Binacional Para el Desarrollo Indigena Oaxaqueño[4] to determine the impact of Madera's closure on the Punjabi population and indigenous farm workers in the affected area found that over 60% of respondents will have to find medical centers outside of the community to receive care. Unfortunately, over half of the indigenous farm workers who responded to the survey reported they do not have a reliable mode of transportation to the nearest hospital. This reduced access to care deepens inequitable outcomes for patients who live in socioeconomically disadvantaged areas.

Over the last 30 years, the 340B program has been a bulwark against this increasing financial pressure for rural and safety-net hospitals. Consistent with Congress' objectives, the 340B program has successfully allowed health care providers to stretch scarce federal resources to better serve their patients and communities. The savings 340B hospitals achieve through purchasing certain outpatient drugs at a discount allows them to provide a range of programs and services that directly benefit their patients. Based on the most recently available data, California's 340B hospitals have provided over $7.1 billion in community benefit.[5] Examples include medication therapy management, diabetes education and counseling, behavioral health services, opioid treatment services, and the provision of free or discounted drugs. It is important to note that 340B supports these programs and services at no cost to taxpayers.

These are services that — without the savings from the 340B program — hospitals may have been forced to eliminate to remain financially viable given inadequate payment from governmental payers. The recent Supreme Court 340B decision underscored this key tenet of the program, noting that it enables hospitals and health care systems to "perform valuable services for low-income and rural communities." *Am. Hosp. Ass'n v. Becerra,* 596 U.S. ___ (2022) (slip op., at 13).

Given California's hospitals' fragile finances and the crucial role 340B plays in maintaining access to care for underserved and at-risk populations, CHA greatly appreciates HHS' proposal to repay hospitals in a lump sum and to include the incremental beneficiary cost sharing in that payment. However, CHA does not share the Department of Health and Human Services' (HHS) belief that this repayment must be done in a budget-neutral manner, which will further degrade all hospitals' ability to maintain their current range of services. Further, CHA believes that HHS should repay hospitals with interest. And finally, CHA is deeply concerned that repayment will come too late for many of California's financially challenged 340B hospitals. Below, please find CHA's detailed comments on the key provisions in the proposed 340B remedy.

Proposed Remedy

HHS proposes to make a one-time lump sum payment to each 340B hospital that would be the same as if HHS manually reprocessed claims for Jan. 1, 2018, through Sept. 27, 2022, at a rate of average sales price (ASP) +6%. The proposed rule indicates that 1,649 340B hospitals received approximately $10.5 billion

[3]https://www.fresnobee.com/news/local/article272712840.html#:~:text=At%20least%20two%20Madera%20patients,told%20The%20Bee%20on%20Friday
[4] https://a27.asmdc.org/press-releases/20230511-community-organizations-release-survey-effects-madera-hospital-closure
[5] 340B Hospital Community Benefit Analysis: California; American Hospital Association; August 2023

less in payments than if Medicare paid these claims at ASP +6%. HHS believes that about $1.5 billion of this amount has already been paid to 340B hospitals for reprocessed claims with dates of service in 2022.

To determine the aggregate amount due to 340B hospitals, HHS determined the difference in payment for separately payable drugs at ASP -22.5% and ASP +6% where the claim included the "JG" modifier that was used to apply the payment adjustment for drugs acquired under the 340B program. Mathematically, HHS indicates this is the equivalent of dividing the ASP -22.5% payment by 0.775 (i.e., removing the 22.5% reduction in payment) and multiplying the result by 1.06 (i.e., providing the 6% additional payment). Where applicable, HHS used an analogous process if the drug was based on wholesale acquisition cost or average wholesale price.

The proposed rule indicates that HHS would pay the hospital the full amount owed, including additional beneficiary coinsurance, while prohibiting the hospital from collecting the additional coinsurance from the beneficiary. HHS cites its equitable adjustment authority as the basis for including the beneficiary coinsurance payments in the amount paid to the hospital. According to HHS, the proposed policy is appropriate in this circumstance "because of the unprecedented scope of the remedy in terms of the amount of money at issue; the number of services, beneficiaries, and claims affected; and the number of years that have passed between the claims and the remedy." **CHA strongly supports the proposal to pay hospitals using a lump sum based on claims billed with the JG modifier. CHA also appreciates that HHS will include the beneficiary cost sharing in the lump sum payment. CHA believes that this approach will minimize the cost burden on Medicare beneficiaries.**

Proposed Budget Neutrality Adjustment

HHS is under the mistaken impression that it is either authorized to seek or required by law to impose a "budget neutrality adjustment" in effectuating the 340B remedy. Instead, HHS has made an intentional *choice* in the proposed rule to rely on sections 1833(t)(2)(E) and 1833(t)(14) of the Social Security Act as its authority for making the remedial repayments. This is ostensibly so that it can then, in turn, insist that these two provisions "require" it to claw back money from hospitals and health systems in the name of "budget neutrality." However, these authorities do *not* support a repayment nor the corresponding "adjustment." HHS should abandon this reverse-engineered effort to achieve recoupment. Instead, HHS should rely on its well-established authority to acquiesce in the Supreme Court's unanimous decision. This acquiescence approach is on firm legal and historical ground, will sever repayment from the recoupment in the face of potential legal challenges by 4,000 affected covered entities, and will bring all stakeholders closer to finally putting this unfortunate saga behind them.

HHS cannot independently rely on its section 1833(t)(2)(E) "adjustment" authority for ensuring equitable payments under the prospective payment system or any common law authority to effectuate a retrospective "budget neutrality adjustment," especially of this size and character. And despite using the word "adjustment" *more than 100 times* in the proposed rule, HHS lacks the legal authority to make the particular proposed $7.8 billion "adjustment." As the Supreme Court recently held in *Biden v. Nebraska* (600 U.S. ___ (2023) (slip op., at 13)), when interpreting similar agency authority to waive or modify discrete statutory provisions, HHS' exercise of a statutory "adjustment" under section 1833 must be moderate or minor, and not transformative of Congress' design. But the size ($7.8 billion) and the manner of the proposed action (*retrospective* clawback from all outpatient prospective payment system (OPPS) entities) is anything but moderate or minor, and instead would fundamentally alter the statutory scheme.

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.

Consequently, even if HHS had the legal authority to pursue a "budget neutrality adjustment" at all — and it does not — then it must, at a minimum, drastically reduce or modify its proposal in the final rule to better align with the far more "minor" or "moderate" agency adjustments permitted by the referenced statutes. In particular, in these "unique circumstances," as HHS rightly calls them, it should consider:

1. Making only a $1.8 billion "adjustment" to correspond to the cost-sharing repayments the agency proposes (and should finalize)
2. Not including CYs 2020-2022 in any "adjustment" because recouping funds that hospitals spent caring for patients during a once-in-a-century pandemic is not "equitable" nor "prospective" under the statute (or, for that matter, sensible public policy)

In addition to these legal defects, HHS' policy justifications 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, California's hospitals had *no choice* but to accept these funds. They should not be adversely impacted in the future by the agency's own unlawful actions in the past.

Over half of California's hospitals experienced negative margins and another 19% had unsustainable margins in 2022. CHA does not expect that to improve in 2023, given that revenue per adjusted discharge[6] lags expense growth. In 2022, labor (+22%), supply (+18%), and pharmaceutical (+19%) cost growth were significantly higher than revenue growth (12%), compared with pandemic levels in 2019. Finalizing the 340B remedy in a budget-neutral manner will add further margin pressure to already financially fragile hospitals, negatively impacting access to care — particularly for Medicare and Medicaid beneficiaries. As discussed above, margin pressure is causing many hospitals to close service lines that generate negative margins to ensure that the hospital can continue operations or not close outright. An unnecessary reduction to OPPS payments would only result in the closure of more services, which would be contrary to the administration's goals of reducing inequitable health outcomes and the overarching aim of the 340B program in fostering a robust safety net. Any additional service closures will have a disproportionately negative impact on access to care for the most disadvantaged.

In California, Medicare and Medi-Cal operating margins are -25% and -26%,[7] respectively. Historically, hospitals have been able to cross-subsidize losses related to providing services that are aligned with the organizations' missions to help the disadvantaged in the communities they serve. However, given that Medicare and Medicaid payments do not cover the cost of providing care and the losses on these patients are rapidly growing as the number of individuals covered by governmental payers increases, we have reached an inflection point. If a hospital continues providing these services in the face of deeper Medicare payment cuts, it will jeopardize the organization's financial viability and access to care for the entire community.

[6] https://www.kaufmanhall.com/sites/default/files/2023-04/CHA-Financial-Impact-Report.pdf
[7] CHA analysis of California Department of Health Care Access and Information data on hospital financial performance

HHS has previously demonstrated its authority and availing options to remedy similar prospective payment system underpayments caused by its own unlawful actions by means of acquiescence and/or without application of budget neutrality. They include:

- *Cape Cod Hospital v. Sebelius* (630 F. 3d 203; D.C. Cir. 2011) — where HHS corrected errors to its wage index calculations by paying eligible hospitals for past claims going back several years via settlement
- *H. Lee Moffitt Cancer Ctr. & Res. Inst. Hosp., Inc. v. Azar* (324 F. Supp. 3d 1; D.D.C. 2018) — where HHS made a retroactive adjustment without applying the budget neutrality requirement to cancer hospitals that received a statutorily mandated adjustment a year later than the law required
- *Shands Jacksonville Medical Center v. Burwell* (139 F. Supp. 3d 240; D.D.C. 2015) — where HHS compensated hospitals for three years of across-the-board cuts with a one-time, prospective increase of 0.6%

Further, the agency does not consistently apply budget neutrality to fix its missteps in other relevant instances. For example, HHS allows for retroactive correction of the wage index without any budget neutrality adjustment if it makes the error and it was not something a hospital could have known or corrected (42 C.F.R. 412.64(k)). In addition, budget neutrality does not apply to changes in enrollment or utilization of drugs when the ASP increases.

CHA respectfully asks that HHS follow the precedents discussed above and finalize the 340B remedy in a non-budget-neutral manner by eliminating any unnecessary reduction to the market basket update in future years. If the agency remedies its illegal action in a budget-neutral manner as proposed, CHA is deeply concerned that it will further exacerbate access issues for not only Medicare beneficiaries but all Californians — particularly those who rely on safety-net facilities, the very same population the 340B program ultimately serves to protect.

Proposed Payment Without Interest

HHS proposes that no interest will be included in the additional payments to 340B hospitals. The proposed rule indicates that the agency does not believe it has the authority to include interest on the additional payments. CHA disagrees with HHS' determination that it does not have the authority; in fact, we believe HHS has an obligation to pay interest on the underpayments pursuant to 42 U.S.C. 1395*l*(j). Accordingly, CHA urges HHS to pay interest starting from the time the Supreme Court made its final determination that the underpayments were unlawful.

Proposed Payment Timing

HHS proposes to issue instructions to the Medicare Administrative Contractors (MACs) to issue a one-time lump sum payment within 60 calendar days. If this rule is finalized, HHS anticipates making additional payments to 340B hospitals at the end of 2023 or the beginning of 2024. CHA notes that Addendum AAA to the proposed rule includes the tentative amounts that HHS owes hospitals as a result of the Supreme Court ruling. While CHA appreciates that HHS needs to allow for additional claims processing to finalize the settlement, CHA is deeply concerned about the financial pressures mounting on California's safety-net hospitals. As discussed above, one of the state's 340B hospitals has already closed and another has filed for bankruptcy. And CHA is aware of others whose financial situation is equally dire.

In light of these risks to access to care for underserved individuals, CHA respectfully asks HHS to accelerate payment of inappropriately withheld amounts for separately payable drugs acquired under the 340B program. This will help ensure access to care for underserved populations that are cared for by safety-net and rural hospitals. Specifically, before HHS finalizes its rule related to the 340B remedy CHA asks that HHS authorize the MACs to make an initial payment to hospitals — that request it — the amounts they are owed based on the proposed rule Addendum AAA. For those hospitals that elect to receive funds immediately, HHS, in the final rule, can instruct the MACs to make an incremental payment based on the final rule and any additional claims that were processed through Sept. 27, 2023.

Payment Amount Dispute Process

While Addendum AAA to the proposed rule illustrates how much each hospital would be due under HHS' proposal, the proposed rule is silent on the process a hospital should use if it identifies a discrepancy in the amount the hospital believes it is owed based on internal records and HHS' accounting of processed claims. **CHA respectfully asks that HHS provide a process whereby each hospital is able to seek redress for any amounts in dispute. Specifically, CHA asks that HHS first pay hospitals as described above. Once the final payment is made in late 2023 or early 2024, hospitals would have 120 days to file a dispute, with supporting evidence, that HHS underpaid the hospital for 340B claims for separately payable drugs provided from 2018-2022.** CHA notes that the time frame and requirement to provide all documentation with a notice of dispute is similar to that used when hospitals request a redetermination of a claim by a MAC. CHA believes this process balances the need for prompt payment of amounts that have been outstanding — in some cases for over five years — against the need for accurate payments. It also provides an orderly process based on a timeline that hospitals and MACs are both already familiar with.

Address Medicare Advantage Underpayment for 340B Drugs

CHA notes that Medicare Advantage Organizations (MAOs) are required by statute to pay hospitals for out-of-network services based on the Medicare PRICER (hereafter PRICER). Additionally, many MAOs in their contracts with in-network hospitals base payments on the PRICER. As a result, 340B hospitals were also subject to a significant reduction in payment for separately payable Part B drugs acquired under the 340B program from 2018–2022 for beneficiaries enrolled in Medicare Advantage (MA). In 2021, 47% of California's Medicare beneficiaries were enrolled in MAOs. Failing to fully rectify the underpayment as a result of HHS' illegal actions for 340B drugs provided to MA beneficiaries from 2018-2022 only compounds the financial stress this illegal policy has placed on safety-net hospitals and jeopardizes access to care for both Medicare and non-Medicare populations who are at risk of inequitable outcomes. **Although it is potentially outside the scope of this proposed rule, CHA urges HHS to take all measures within its authority to incorporate underpayments for 340B drugs provided to MA beneficiaries into the final remedy.**

On Dec. 20, 2022,[8] HHS sent a reminder to MAOs about the Supreme Court's decision in Am*erican Hospital Association v. Becerra* and the district court's Sept. 28, 2022, order vacating the differential payment rates for 340B-acquired drugs in the CY 2022 OPPS final rule. CHA is aware that some MAOs have not appropriately respected those decisions by repaying hospitals what they are owed. HHS should

[8] https://www.cms.gov/files/document/cmsopps340bupdate508g.pdf

identify a mechanism to pay hospitals directly if MAOs do not have (or have not received) the funds to facilitate the required repayments.

As HHS is aware, the reduction of payments for 340B drugs from 2018-2022 was done in a budget-neutral manner. The projected reduction in 340B payments was applied to the market basket update as a positive budget neutrality adjustment. For MAOs that are contracted with hospitals based on the PRICER, this would have simply shifted dollars from one OPPS category (e.g., separately payable 340B drugs) to another (e.g., items and services paid based on an ambulatory payment classification). As a result, in theory, MAOs that contract with hospitals based on the PRICER should not have experienced an increase in capitated revenue from Medicare nor a significant decrease in claims payments to hospitals. However, in instances where MAOs contract with hospitals based on a capitated rate for hospital services[9] and pharmaceuticals are carved out of the capitated rate and paid based on the PRICER, the impact to the MAO may not have been budget neutral if the capitated rate for hospital services was not adjusted to reflect the increase in outpatient payments in the PRICER that resulted from CMS' illegal reduction in payments for 340B drugs.

CHA respectfully asks the agency to explore options it can use to directly pay eligible hospitals appropriately for separately payable 340B drugs provided to MA members from 2018-2022. Specifically, CHA asks HHS to use its prompt payment authorities under 42 U.S.C. 1395w-27(f) to directly pay eligible hospitals. Instead of requiring the plans to pay hospitals a lump sum settlement for 340B claims, HHS could pay hospitals directly without passing additional funds through to MAOs (or withholding funds without merit). CHA believes that 42 U.S.C. 1395w-27(f)(2) allows for this, as described below.

> *(2) Secretary's option to bypass noncomplying organization*[10]
> *In the case of a Medicare+Choice eligible organization which the Secretary determines, after notice and opportunity for a hearing, has failed to make payments of amounts in compliance with paragraph (1), the Secretary may provide for direct payment of the amounts owed to providers and suppliers (or, in the case of a Medicare+Choice private fee-for-service plan, amounts owed to the enrollees) for covered services and supplies furnished to individuals enrolled under this part under the contract. <u>If the Secretary provides for the direct payments, the Secretary shall provide for an appropriate reduction in the amount of payments otherwise made to the organization under this part to reflect the amount of the Secretary's payments (and the Secretary's costs in making the payments)</u>*[11]*<u>.</u>*

CHA notes that 42 U.S.C. 1395w-27(f)(2) requires the Secretary to "provide for an appropriate reduction in the amount of payments otherwise made to the organization … to reflect the amount of the Secretary's payments." However, for out-of-network MA beneficiaries and in instances where MAOs' contracts with hospitals are based on the PRICER, MAOs' "non-compliance" to make a direct payment is a result of the Secretary not providing sufficient funds for the MAO to make a lump sum settlement to eligible hospitals for separately payable Part B drugs acquired under the 340B program from 2018-2022 provided to MAO enrollees. Therefore, there is nothing for the Secretary to withhold from these MAOs.

[9] Includes inpatient, outpatient, and other facility-based services.
[10] https://www.govinfo.gov/content/pkg/USCODE-2019-title42/pdf/USCODE-2019-title42-chap7-subchapXVIII-partC-sec1395w-27.pdf
[11] Emphasis added.

CHA appreciates the opportunity to comment on the proposed 340B remedy for the years 2018-2022. If you have any questions, please do not hesitate to contact me at cmulvany@calhospital.org or (202) 270-2143.

Sincerely,
/s/

Chad Mulvany
Vice President, Federal Policy