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August 7, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

***Re: Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022* (RIN 0938-AV18) (July 11, 2023)**

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners—including more than 270,000 affiliated physicians, 2 million nurses and other caregivers—and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the Department of Health and Human Services' (HHS) attentive approach to the proposed remedy following the Supreme Court's decision in *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022).

The AHA strongly supports many features of the proposed remedy, including: 1) a one-time lump sum repayment to hospitals for underpayments for outpatient drugs purchased under the 340B Drug Pricing Program between calendar years (CYs) 2018 and 2022; 2) the agency's decision to repay what hospitals would have received in beneficiary cost-sharing; and 3) the proposed methodology for calculating what 340B hospitals are owed, which minimizes administrative burden. Last June, shortly after the Supreme Court issued its decision, AHA President and CEO Richard J. Pollack wrote to HHS Secretary Xavier Becerra asking that HHS fully and promptly repay 340B hospitals because they, like other hospitals in the field, are "weathering significant financial challenges." The proposed remedy achieves this goal. **These features should be finalized as soon as possible.**

At the same time, the AHA is greatly disappointed that HHS chose to propose "budget neutrality adjustments" to offset this legally-required remedy. The statutes that HHS relies on in its proposed rule do not give it the authority to make a "budget neutrality adjustment." Nor do they require budget neutrality as a matter of law. **Thus, contrary to**

suggestions in the proposed rule, HHS has both the legal obligation and legal flexibility to not seek a clawback of funds that hospitals received as a result of HHS' own mistakes and have long since spent on patient care.

For example, HHS made an intentional choice to rely on sections 1833(t)(2)(E) and 1833(t)(14)(H) of the Social Security Act as its proposed authority for making the remedial repayments, 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." *See* Medicare Program; Hospital Outpatient Prospective Payment System: Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018–2022, 88 Fed. Reg. 44,078, 44,087 (proposed July 11, 2023) (hereinafter "Proposed Rule"). As explained below in Section II.B, we do not believe that there is legal authority for HHS to rely on these two sections to make the required repayments. Even if HHS disagrees, the proposed rule's reliance on these authorities was undeniably a *choice* that HHS made; it was not a choice required by law. **HHS should abandon this reverse-engineered effort to justify recoupment.** Not only do these provisions fail to provide legal authority for the repayment or corresponding retrospective recoupment, but a far simpler legal authority exists for the remedial repayments: acquiescence to the Supreme Court's decision. **HHS should rely on its acquiescence authority to make the repayments required under *American Hospital Association v. Becerra*, as it did for the January 1, 2022 through September 27, 2022 period, and as it has done many times in the past in connection with other judicial decisions.**

In addition, even if HHS had the legal authority for its "budget neutrality adjustment"—and it does not—its proposal to retrospectively recoup $7.8 billion from all hospitals participating in the Outpatient Prospective Payment System (OPPS) is unlawful because that recoupment does not qualify as an "adjustment" under the plain meaning of that term. The Supreme Court recently interpreted a similar term in *Biden v. Nebraska*, No. 22-506, Slip Op. at 13 (June 30, 2023), and held that it means "to change moderately or in minor fashion." An "adjustment" of this size, scope, and nature is in no way moderate or minor. **It is likely that HHS did not have time to factor in *Biden v. Nebraska* before issuing its proposed rule, but its final rule must account for it. If HHS chooses to seek a repayment at all—and it should not—then it must choose a far more moderate one, such as 1) one that mirrors the $1.8 billion adjustment proposed for beneficiary cost-sharing; or 2) one that completely excludes CYs 2020 to 2022, the years in which hospitals and health systems were using these funds to battle a once-in-a-century pandemic.**

To be clear, the AHA appreciates HHS' attempt to draft an "offset [that] is not overly financially burdensome on impacted entities," including by proposing a prospective 16-year offset period with a delayed start. Proposed Rule at 44,087. **If HHS chooses to pursue a "budget neutrality adjustment," it should finalize these features, *i.e.*, the "adjustment" should begin in 2026 (or later) and be spread out over 16 years. But HHS should not pursue *any* "budget neutrality adjustment" in the final rule, or, at**

the very least, it must pursue a far more moderate one than the proposed $7.8 billion "adjustment."

In the end, the AHA is thankful that there is finally a light at the end of the tunnel for 340B hospitals that HHS underpaid for years. The proposed lump sum repayments will provide critical resources to these hospitals as they continue to care for America's most vulnerable patients. As HHS finalizes this proposal, however, we respectfully urge it to avoid exposing itself to potential litigation from any of the thousands of OPPS entities subject to the proposed "budget neutrality adjustment," which would prolong this unfortunate saga even further. **Accordingly, in considering the AHA's comments, we sincerely hope that HHS gives due weight to the government's important interest in finality**.

I. HHS SHOULD FINALIZE THE PROPOSED REMEDIAL REPAYMENT

The AHA fully supports the proposed rule's "way to remedy [HHS'] payment policy for 340B-acquired drugs for the period from CY 2018 through September 27th of CY 2022." Proposed Rule at 44,083. The proposal to make "one-time lump sum payments to affected 340B covered entities calculated as the difference between what they were paid for 340B drugs (ASP minus 22.5% percent or an adjusted WAC or AWP amount) during the relevant time period (from CY 2018 through September 27th of CY 2022) and what they would have been paid had the 340B payment policy not applied" is undoubtedly the best remedial approach. Likewise, the AHA unequivocally supports HHS' proposal to pay 340B hospitals what they would have received in beneficiary cost-sharing had the unlawful 340B payment policy not been in effect. **These aspects of the proposed rule should be finalized as soon as possible.**

As the proposed rule discusses, these remedial features achieve several important goals:

First, the proposal is responsive to the Supreme Court's holding that HHS' prior payment policy was unlawful. To comply with that unanimous decision, HHS must apply the default rate (ASP plus 6%). The proposed rule does that.

Second, the proposal "comes as close to providing 340B covered entities with make-whole relief as CMS can reasonably accomplish." *Id*. The AHA agrees that "[a]ssuming hospitals properly assigned the billing codes discussed below when submitting their CY 2018 through 2022 claims, CMS expects the remedy payment to each 340B covered entity for 340B-acquired drugs to be the same as if CMS manually reprocessed those claims." *Id*. What's more, the proposed rule rightly accounts for what hospitals would have received in beneficiary cost-sharing. *See id*. at 44,085-44,086 (proposing a cost-sharing repayment "in these unique circumstances in part 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"). By repaying the HHS

underpayments *and* cost-sharing components, the proposed rule is the best way to fully compensate 340B hospitals for HHS' unlawful policies.

Third, the AHA has consistently asked HHS to repay 340B hospitals promptly. In proposing a one-time lump sum payment, including cost-sharing, HHS achieves that end. By the time they are repaid under this proposal, 340B hospitals will have suffered from these underpayments for six years. It is far past time for them to receive these funds. A one-time lump sum payment ensures that they will be repaid promptly.[1]

In addition, although the AHA disagrees with HHS' determination that it does not have the authority to pay interest on the underpayments and urges HHS to pay interest starting from the time the Supreme Court made its final determination that the underpayments were unlawful,[2] there can be no doubt that a protracted repayment process would undoubtedly require interest payments under 42 U.S.C. § 1395l(j). As such, the proposed one-time lump sum repayment appropriately minimizes the impact on the public fisc.

Fourth, as HHS recognizes, the proposed rule is administratively simple for hospitals and the agency. It wisely does not impose the "massive burden that would be associated with manually reprocessing all claims." *Id*. The AHA agrees with HHS that

> [r]eprocessing such an unprecedentedly large volume of claims and issuing payment to affected providers in a timely fashion would impose an

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[1] HHS seeks comment on the proposed timeframe for repayment. It states that "we believe 60 calendar days is necessary for the MACs to accurately and precisely make these payments to individual hospitals." Proposed Rule at 44,085. The AHA defers to HHS' judgment on how fast it can accomplish the task, but emphasizes that payments should be made *as quickly as possible* and in no more than 60 days. If comments from Medicare Administrative Contractors or others indicate that a shorter time period (*e.g.*, 30 or 45 days) is feasible, then the final rule should adopt that timeframe.

Likewise, if time considerations make it necessary to sever this proposed rule into two rules (*i.e.*, one on repayment and one on recoupment), then HHS should do that to speed up the repayment process—especially because recoupment is not proposed to begin until at least 2025. So long as the repayment component of the rule is finalized on the proposed timeframe and hospitals are reimbursed by late 2023, the AHA has no objection to HHS withdrawing the "budget neutrality adjustment" portion of this proposed rule so that it can take all the time that it needs to sort through the many legal, public policy, and data-related defects described below.

[2] *See* Letter from Melinda Reid Hatton, General Counsel and Secretary, American Hospital Association to Samuel Bagenstos, General Counsel, Department of Health and Human Services (Feb. 1, 2023), *at* https://www.aha.org/system/files/media/file/2023/02/aha-requests-meeting-with-hhs-to-discuss-340b-remedial-payment-outlines-principles-to-accelerate-process-letter-2-1-23.pdf.

> immense administrative burden on CMS, its contractors, and providers. We accordingly believe that this approach is not feasible in this case.… The large quantity of claims and the amount of time required to reprocess them while continuing normal claims processing likewise would not result in timely payments or adjustments to hospitals.

Id. at 44,082. The proposed methodology of calculating remedy payments and the timing of those repayments also are administratively simple.[3]

Fifth, the proposed repayment of beneficiary cost-sharing appropriately protects patients. As the proposed rule notes, if HHS 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." *Id*. Patients do not deserve this "surprise." Similarly, hospitals and health systems should not be forced to demand that their patients pay for HHS' mistakes so long after HHS committed them. HHS' proposal to cover the cost-sharing portion of the underpayments prevents these consequences.

There are several other reasons not discussed in the proposed rule why this proposed remedy is the best approach to repaying hospitals and health systems. HHS should bear these in mind as well.

Most important, America's hospitals and health systems are still struggling financially. Hospitals and health systems lost hundreds of billions of dollars during the COVID-19 pandemic, bringing many to the cusp of collapse and forcing others to close altogether, especially in rural communities. Last year was "the worst financial year since the start of the pandemic. Approximately half of U.S. hospitals finished the year with a negative margin as growth in expenses outpaced revenue increases." *See Kaufman Hall*, NATIONAL HOSPITAL FLASH REPORT: JANUARY 2023, *at* https://www.kaufmanhall.com/sites/default/files/2023-01/KH_NHFR_2023-01.pdf. And those struggles continue today, as persistent financial headwinds still face the hospital field. Most hospitals across the country continue to operate on negative or very thin margins that make providing care and investing in their workforce very challenging day to day. A one-time lump sum payment will play a small part in easing those continuing financial challenges.

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[3] If the AHA has any quibble with HHS' proposed methodology, it is that repayment for 2022 could be made even more administratively simple. **In conducting our calculations about the size of potential 2022 repayments, it appears that HHS's estimates are low (possibly by several hundred million dollars). With reprocessing for CY 2022 still ongoing, we would recommend that HHS clearly instruct Medicare Administrative Contractors (MACs) to repay 340B hospitals in a mass adjustment for claims going back to January 1, 2022.** All other claims prior to CY 2022 would be included in the lump sum repayment as proposed by CMS.

More specifically, during the two prior comment periods on a proposed remedy, numerous 340B hospitals described how the failure to fully and promptly repay would jeopardize their ability to provide important patient services. For example, Temple University Hospital in Philadelphia, Pennsylvania stated:

> 340B savings enable Temple University Hospital to make significant investments in our disadvantaged community, such as our plans to develop a dedicated hospital facility for women and infants. Our future women's hospital will provide care to the approximately 2,200 women who deliver their infants at Temple University Hospital. About 37% live below the federal poverty level (FPL), compared with 15% in the United States; 17% did not graduate from high school, compared with 12% in the United States and 73% identify as non-white. Prompt repayment of our 340B savings will enable us to facilitate the development of our hospital facility for women and infants, as well as our ability to maintain programs to address the opioid epidemic, the gun violence crisis and other complex medical and social challenges facing North Philadelphia citizens.

Letter from Michael A. Young, President & CEO, Temple University Health System to the Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services, Re: CMS-1772-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (Sep. 8, 2022).

Likewise, Bronson Healthcare Group in Kalamazoo, Michigan explained:

> The lost revenues [from HHS's unlawful 340B underpayments] contributed to the need for our organization to conduct a reduction in force in 2019. In total, the annualized impact of these reductions represented approximately 90 FTEs. These reductions had negative impacts on clinical care teams and the organization's ability to provide access to healthcare to underserved populations.

Letter from Troy Shirley, System Director of Pharmacy, Bronson Healthcare to the Honorable Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services, Re: CMS-1772-P.

HHS has all of these comments, and the AHA need not repeat them here. **But the basic point remains: Anything short of a one-time lump sum repayment would impede the ability of 340B hospitals to provide vital health care services to their patients and communities**.

Finally, it is important to emphasize the positive impact that the proposed remedy will have on "disadvantaged, vulnerable, or marginalized communities" Presidential Memorandum § 2(b)(ii), 86 Fed. Reg. 7223, 7223 (Jan. 26, 2021); *see* Memorandum from Richard L. Revesz, Administrator, Office of Information and Regulatory Affairs to

Regulatory Policy Officers at Executive Departments and Agencies Re: Implementation of Modernizing Regulatory Review Executive Order 2 (Apr. 6, 2023) ("regulatory analysis, as practicable and appropriate, shall recognize distributive impacts and equity, to the extent permitted by law"). As the Supreme Court recognized: "340B hospitals perform valuable services for low-income and rural communities but have to rely on limited federal funding for support." *Am. Hospital Ass'n v. Becerra*, 142 S.Ct. 1896, 1905-1906 (2022). And as former Congressman Henry A. Waxman has written, "340B hospitals are also an important part of our national efforts to improve health care equity for patients who historically have faced challenges accessing care and achieving positive health outcomes." Henry A. Waxman, 30 Years Of 340B: *Preserving The Health Care Safety Net*, HEALTH AFFAIRS (Dec. 7, 2022), *at* https://www.healthaffairs.org/content/forefront/30-years-340b-preserving-health-care-safety-net. 340B disproportionate share hospitals (DSH) also play a disproportionate role in serving communities of color, who themselves face disproportionate illness burden and barriers to care. Thus, any policy that protects 340B hospitals will protect "disadvantaged, vulnerable, or marginalized communities." Put simply, the proposed repayment plan manifestly fulfills the goals of President Biden's Executive Order on Modernizing Regulatory Review and should be finalized on that basis as well.

For all of these reasons, the AHA is grateful for and fully endorses HHS' decision to repay 340B hospitals fully, promptly, and in the simplest manner available. We encourage HHS to finalize these portions of the proposed rule as soon as possible.[4]

II. HHS MUST NOT FINALIZE THE PROPOSED BUDGET NEUTRALITY "ADJUSTMENT"

To "neutralize" the remedial payments to 340B hospitals, HHS proposes to "reduce all payments for non-drug items and services to all OPPS providers … by 0.5 percent each year until the total offset is reached (approximately 16 years)." Proposed Rule at

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[4] On December 20, 2022, CMS sent a reminder to Medicare Advantage Organizations (MAOs) about the Supreme Court's decision in *American Hospital Association v. Becerra* and the district court's September 28, 2022 order vacating the differential payment rates for 340B-acquired drugs in CY 2022. *See* Letter from Jennifer R. Shapiro, Director, Medicare Plan Payment Group, CMS to All Medicare Advantage Organizations, Prescription Drug Plans, Cost Plans, PACE Organizations, and Demonstrations, Re: Hospital Outpatient Prospective Payment System Update on Payment Rates for Drugs Acquired through the 340B Program - INFORMATIONAL for MAOs (Dec. 20, 2022). Since then, the AHA has been made aware by numerous members that commercial MAOs have not appropriately respected those decisions by repaying hospitals what they are owed. **Although it is potentially outside the scope of this proposed rule, the AHA urges HHS to take all possible measures within its authority to ensure MAO compliance.** One option is for HHS to use its prompt payment authorities under 42 U.S.C. 1395w-27(f) to ensure MAO compliance with this remedy. If the final rule does not rely on this authority to address this problem, the AHA intends to further address this subject with HHS after the remedial rule is finalized.

44,087. In its view, a "budget neutrality adjustment is statutorily required and, even if not statutorily required, warranted as a matter of sound public policy." *Id*. at 44,081; *see id*. at 44,082 (same). **But neither law nor policy supports this proposed "budget neutrality adjustment," and the final rule should not include it. If the agency disagrees and chooses to pursue an "adjustment," then that $7.8 billion "adjustment" should be substantially reduced to: a) correspond only to the size of the $1.8 billion in proposed cost-sharing adjustments; or b) exclude CY 2020-2022—the years when hospitals and health systems were on the front lines of a once-in-a-century pandemic that caused adverse financial impacts that last to this day.**

Before explaining why HHS cannot and should not finalize this proposed "budget neutrality adjustment," it is important to underscore two critical areas of agreement between the agency and AHA. *First*, the proposed rule correctly recognizes that any offset would be "financially burdensome" to hospitals, "especially those in rural communities." *Id*. at 44,087. Hospitals relied on and have already spent the payments HHS made between 2018 and 2022. For this reason, the proposed rule appropriately contains a "delayed offset" that applies prospectively "over a period of time," which the agency predicts will be 16 years. *Id*. *Second*, the AHA agrees that HHS should not "revise retroactively [its] estimated expenditures for CY 2018 through 2022," *id*. at 44,088, which would result in recouping even more from hospitals than $7.8 billion proposed in this rule. Recouping even more from hospitals would be fundamentally unfair because it would make them pay for *two* of the agency's mistakes: the unlawful payment reductions that necessitate this remedy *and* the agency's incorrect predictions from CY 2018 to CY 2022 under the prospective payment system. *Id*. ("[O]ur CY 2018 through 2022 predictions are the primary reasons that our proposed method of budget neutralization would not fully align with the money we predict the Part B Trust Fund would pay out in lump sum payments for 340B-acquired drugs as a result of this remedy.").

If the agency is going to pursue a "budget neutrality adjustment"—which it should not—it must include these proposed features. Recoupment must be (1) prospective, (2) extended for 16 years or more[5], and (3) delayed in its start until 2026 or later. And providers must not be forced to pay a penny more than the proposed $7.8 billion. But, as noted above and explained further below, HHS may not legally and should not as a matter of policy seek *any* "budget neutrality adjustment," or, at the very least, it must seek a substantially reduced one.

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[5] As explained below (at 29 n.18) there is a significant discrepancy in HHS's OPPS data, which could impact how long it would take for the agency to effectuate any recoupment. The agency's apparent failure to accurately calculate this information is reason alone to forego the "budget neutrality adjustment." At a minimum, this data discrepancy requires the agency to specify a specific time period (*i.e*., 16 years or more), if it chooses to recoup funds at all, and tweak the annual "adjustment" amount accordingly.

A. HHS Should Rely On Its Acquiescence Authority To Repay 340B Hospitals

HHS' perceived need to make a "budget neutrality adjustment" stems from its mistaken reliance on sections 1833(t)(2)(e) and (t)(14)(H) to make repayments to 340B hospitals. But as explained below in Section II.B, those provisions do not authorize HHS to make repayments.

By relying on these two statutes for authority, it appears that the proposed rule is trying to reverse-engineer a legal authority for the remedial repayments that will then allow it to recoup funds under the guise of a budget neutrality "requirement." *See* Proposed Rule at 44,087. That is the wrong way to approach this issue—and not only because sections 1833(t)(14)(H) and 1833(t)(2)(E) cannot provide authority for the repayments. *See infra* at Section II.B. HHS should rely on the best and most straightforward authority to support repayment, and treat the legal question of whether to offset the remedial payments or recoup prior payments separately. Put another way, HHS certainly should not let the tail of budget neutrality wag the dog of remedial repayments, as reliance on this reverse-engineered pair of legal authorities appears to do.

Fortunately, a far simpler and incontestably-lawful approach is available to repay 340B hospitals the money they are owed. HHS should acquiesce in the Supreme Court's decision and repay hospitals accordingly—an approach it has adopted in the past. Unlike the proposed reliance on sections 1833(t)(14)(H) and 1833(t)(2)(E), this approach has the benefit of being legal. *See generally Grant Medical Center v. Hargan*, 875 F.3d 701, 701 (D.C. Cir. 2017) ("Appellants, hospitals in the Sixth Circuit, challenge CMS' decision to acquiesce to the Sixth Circuit's ruling. Given that obeying judicial decisions is usually what courts expect agencies to do, the hospitals face an uphill battle. The district court found that the agency acted reasonably, and we agree."). And the case for acquiescence is especially strong here because the Supreme Court has ruled, and "'the law forming the basis for the obligation to acquiesce is no longer in flux.'" *Johnson v. U.S. R.R. Retirement Bd*., 969 F.2d 1082, 1092 (D.C. Cir. 1992) (quoting Samuel Estreicher & Richard Revesz, *Nonacquiescence by Federal Administrative Agencies*, 98 YALE L.J. 679, 725 (1989)). Significantly, it makes no difference that the Supreme Court did not specify or order a particular remedy. Because the Court unmistakably held that 340B hospitals must be paid at the ASP +6% rate, HHS can simply acquiesce in that holding and repay accordingly.

In fact, HHS *already* acquiesced to the Supreme Court's ruling so that it could provide *some* remedial payments. As the proposed rule observes, "a large portion of the CY 2022 340B drug claims for dates of service between January 1, 2022, and September 27, 2022, have already been remedied as a result of being processed or reprocessed at the default drug payment rate." Proposed Rule at 44,088. But no regulation relying on sections 1833(t)(14)(H) and section 1833(t)(2)(e) authorized this remedy. Nor did the district court's September 28, 2022 forward-looking order. *See* Order, *Am. Hospital Ass'n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 78. ("ORDERED that the drug reimbursement rate for 340B hospitals in the 2022 OPPS Rule is hereby

VACATED with respect to its *prospective application*." (emphasis added)). The only authority for processing these nine months of 2022 remedial payments was HHS' acquiescence in the Supreme Court's June 2022 decision holding the payment rate to be unlawful—and that decision technically only applied to CYs 2018 and 2019, making the acquiescence even more noteworthy.[6]

Critically, that was not the only time HHS has acquiesced to judicial rulings or clear statutory violations. To take just a few historical examples:

- In *Baystate Medical Center v. Leavitt*, 545 F. Supp. 2d 20 (D.D.C. 2008), the court required CMS to correct previously undisclosed errors and omissions in the calculation of the Medicare Part A/SSI fraction used to calculate the DSH payment, finding that CMS had not calculated the Medicare Part A/SSI fraction using the best available data, as required under the Medicare DSH statute through its reference to the "number" of hospitals days rather than "estimate." *Id*. at 43. The court ordered the agency to recalculate the hospital's SSI fractions and DSH adjustments. *See id*. CMS then acquiesced to the *Baystate* decision through the issuance of a directive that made the required correction for prior cost years where the issue was properly appealed or not yet settled. The agency did not undertake notice-and-comment rulemaking to adopt the Ruling addressing past years. *See* CMS Ruling No. 1498-R (Apr. 28, 2010).

- In 2011, CMS acquiesced through another Ruling to multiple district and circuit court decisions all of which had uniformly held that that CMS' methodology for calculating the hospice cap violated the plain language of the Medicare statute. In CMS Ruling 1355-R, CMS provided a process for recalculating the erroneously determined hospice payments for any hospice with "a properly pending appeal . . . in any administrative appeals tribunal . . . that seeks review of an overpayment determination for any hospice cap year . . . ending on or before October 31, 2011." CMS Ruling No. 1355-R.

- In December 2020, after concluding it had made a clear legal error, just as the Supreme Court identified here, CMS instructed Medicare contractors to restore Part C Graduate Medical Education funding to affected hospitals that CMS had improperly reduced going back nearly two decades, and applied the change not only to hospital cost years under appeal, but more broadly to "each and every" affected cost year that was within the reopening window at the time. *See* CMS Pub. 100-20, Transmittal No. 10520 (Dec. 14, 2020).

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[6] Indeed, in the context of explaining why it is not asking beneficiaries to supplement their copayments, HHS appears to recognize that its proposal entails *remedy* payments—not ordinary OPPS payments—thereby making the case for acquiescence even stronger. *See* 88 Fed. Reg. at 44,085 ("Because these payments are *remedy payments* . . ., we do not believe the[y] would be 340B drug payments subject to beneficiary copayments." (emphasis added)).

- In several similar circumstances, HHS acquiesced to judicial rulings by entering settlements with hospitals rather than issuing new regulations. For instance:

    - CMS entered into a settlement agreement with affected hospitals following a decision against the agency regarding the treatment of Section 1115 waiver days in the DSH calculation. *See HealthAlliance Hospitals, Inc. v. Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018); *see also* Clerk's Orders Granting Extensions To Accommodate Pending Mediation, dated March 26, 2019, April 18, 2019, and June 13, 2019, *HealthAlliance Hosps., Inc. v. Azar*, No. 18-5372 (D.C. Cir.); Joint Stipulation of Dismissal dated August 29, 2019, HealthAlliance Hosps., No. 18-5372 (D.C. Cir.).

    - In *Cape Cod Hospital v. Sebelius*, 630 F.3d 203 (D.C. Cir. 2011), the D.C. Circuit Court vacated CMS' rule providing for the calculation of the rural floor budget neutrality adjustment to the inpatient prospective payment system payment rates, finding that CMS was not permitted, under section 4410 of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, 402, to ignore errors in the prior year in calculating rural floor budget neutrality adjustments for successive years because doing so would result in aggregate payments less than would have been made if the adjustment had not been in place, contrary to the statutory requirements on how to calculate the adjustment. CMS entered a global settlement for all prior cost years that were appealed. 76 Fed. Reg. 51,476, 51,799 (Aug. 18, 2011).

Clearly, HHS has acquiesced in far less "unique circumstances" than these, *see* Proposed Rule at 44,085, and these "unique circumstances" certainly justify exercising that authority again.

Ultimately, given this long pattern of acquiescence—including in this very case—the agency should not overcomplicate matters by relying on two statutory provisions that neither authorize nor require it to make the mandated repayments. Nor should it overcomplicate matters by seeking to reverse-engineer a way to compel "budget neutrality adjustments." The best path here is the simplest one: relying on acquiescence to the Supreme Court's decision as authority for the prompt repayment of hospitals that it has already proposed.

B. HHS Cannot Rely On Sections 1833(t)(2)(E) and 1833(t)(14) To Reverse Engineer The Legal Authority To Seek a "Budget Neutrality Adjustment"

At various points throughout the proposed rule, HHS suggests that it is legally required to make a "budget neutrality adjustment." That is incorrect for several reasons.

The proposed rule insists that HHS is required to seek a "budget neutrality adjustment" because it relies on certain statutory provisions for its authority to repay 340B hospitals that, in turn, require budget neutrality. It states: "we believe that sections 1833(t)(2)(E) and 1833(t)(14) of the Act, *under which we propose to make this proposed remedy payment*, are properly read to require budget neutrality." *Id*. at 44,087 (emphasis added); *id*. at 44,083 ("We propose to make the remedy payments relying principally on: (1) our rate-setting authority under section 1833(t)(14) of the Act; and (2) our equitable adjustment authority under section 1833(t)(2)(E) of the Act."). **But make no mistake: HHS is making a *choice* to rely on those provisions for its proposed remedial authority. It could easily choose to rely on the far more straightforward acquiescence authority discussed above, but that would defeat its ill-advised effort to recoup funds from hospitals to pay for the agency's own mistakes. For that reason alone, it should abandon this reverse-engineered, discretionary effort to justify a "budget neutrality adjustment."**

To make matters worse, these two provisions do *not* provide legal authority for the repayments at issue here or any corresponding "budget neutrality adjustment." For starters, the proposed rule relies on the portion of section 1833(t)(14)(H) addressing "[a]dditional expenditures resulting from this paragraph." But those payments do not "result [] from" any statutory paragraph at this point in time. Instead, they "result from" the Supreme Court's unanimous decision invalidating five years of unlawful agency action. Nor is there anything "additional" about the remedial repayments. *See* WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 24 (2002) (defining "additional" to mean "existing or coming by way of addition; added, further," and defining "addition" to mean "the result of adding"). Those payments are what 340B hospitals should have been paid in the first place. *See* Proposed Rule at 44,087 ("[I[t is our best effort to implement the policy that would have been in effect had the 340B policy never been implemented in the first place."). The amounts owed to 340B hospitals are not "added" to anything; they are what hospitals were owed as if—as the proposed rule puts it—HHS could "turn[] back the clock to restore the position in which we would have been absent the policy the Supreme Court invalidated." *Id*. at 47,084.

More fundamentally, section 1833(t)(14)(H) expressly incorporates "paragraph (9)" for HHS' asserted budget neutrality requirement. *Cf*. *Am. Hosp. Ass'n v. Becerra*, Br. for the Respondents, at 27 (U.S. No. 20–1114) ("But paragraph (14) is not an island."). But as the AHA has repeatedly explained in legal briefs, comments on HHS proposed rules, and letters to HHS officials, the text of paragraph (9) makes clear that budget neutrality is a *prospective* exercise.[7] To briefly reiterate, paragraph (9) directs CMS to annually

[7] The AHA incorporates those many previous submissions in this comment. *See, e.g.*, Reply In Support Of Plaintiffs' Motion to Hold Unlawful And Remedy Defendants' Past Underpayment of 340b Drugs, *Am. Hospital Ass'n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 78 at 14-17 (Sep. 21, 20222); Motion to Hold Unlawful And Remedy Defendants' Past Underpayment of 340b Drugs,

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). Any such 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).[8] Put simply, the plain text of paragraph (9) says nothing about past years or retrospective

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Am. Hospital Ass'n v. Becerra, Case No. 1:18-cv-2084, Dkt. 69 (Sep. 21, 20222); Letter from Stacey Hughes, Executive Vice President, American Hospital Association to The Honorable Chiquita Brooks-LaSure, Administrator Centers for Medicare & Medicaid Services, Re: CMS–1772–P (Sep. 13, 2022), *at* https://www.aha.org/lettercomment/2022-09-13-aha-comments-opps-and-asc-payment-system-proposed-rule-cy-2023; Letter from Melinda Reid Hatton, General Counsel and Secretary, American Hospital Association to Samuel Bagenstos, General Counsel, Department of Health and Human Services (Feb. 1, 2023), *at* https://www.aha.org/system/files/media/file/2023/02/aha-requests-meeting-with-hhs-to-discuss-340b-remedial-payment-outlines-principles-to-accelerate-process-letter-2-1-23.pdf.

[8] *See Am. Hosp. Ass'n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (budget neutrality under the OPPS avoids increases or decreases in "overall *projected expenditures for the next year*" (emphasis added); 2021 OPPS Rule, 85 Fed. Reg. at 86,054 ("OPPS budget neutrality is generally developed on a *prospective basis* by isolating the effect of any changes in payment policy or data under the OPPS with all other factors held constant." (emphasis added)); *see generally Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) ("In amending the statute, both Houses of Congress made it abundantly clear that this authority was to be exercised on a *prospective* basis only: '[The authority] to set limits on costs ... would be exercised on a *prospective*, rather than retrospective, basis so that the provider would know in advance the limits to Government recognition of incurred costs and have the opportunity to act to avoid having costs that are not reimbursable.' Senate Report at 188; House Report at 83"); *Washington Hosp. Ctr. v. Bowen*, 795 F.2d 139, 142 n.2 (D.C. Cir. 1986) (explaining that a prospective payment system is "not subject to retroactive adjustment"); *Louisiana Dep't of Health & Hosps. v. U.S. Dep't of Health & Human Servs*., 566 F. App'x 384, 387 (5th Cir. 2014) (discussing the differences between prospective and retrospective payment systems); *Alexander County Hosp. v. Bowen*, 692 F.Supp. 606, 609 (W.D.N.C. 1988) ("Thus, under both the APA and the Medicare Act, the Secretary's authority for rulemaking is prospective, not retrospective. To hold otherwise would give the Secretary unfettered discretion in enacting regulations that give retroactive effect to any or every change that is made in formulas for determining reimbursable costs."); *cf*. *Paladin Community Mental Health Center v. Sebelius*, 684 F.3d 527, 531 n.3 (5th Cir. 2012) ("[F]orcing the Secretary to retroactively alter payment rates for various covered services—*e.g.*, payment rates that are adjusted annually and are required to remain budget neutral—would likely wreak havoc on the already complex administration of Medicare Part B's outpatient prospective payment system.").

clawbacks; instead, it addresses only future estimates and forward-looking periodic reviews.[9]

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[9] The agency's changed position regarding the term "year" in section 1833(t)(9) further weakens its assertions of recoupment authority. *Compare Am. Hosp. Ass'n v. Becerra,* Br. for the Respondents, at 30 (U.S. No. 20–1114), *with* Proposed Rule at 44,087. After reviewing the government's current position in depth, the AHA has humbly come to the conclusion that the government's original position on this particular point was the better one. In reviewing the proposed rule's discussion of the issue, it became clear that HHS' effort to backtrack from its earlier reading of "year" further underscores the agency's flawed effort to reverse engineer a clawback.

The proposed rule states that HHS is abandoning its prior interpretation of the statutory term "year" "not by seeking to budget neutralize payments across a period of years rather than in a particular ''year', but instead by adjusting payment rates for each year from 2018 to 2022 *to account for the Supreme Court's decision*." *Id*. (emphasis added). As an initial matter, that raises the question: why not just acquiesce to the Supreme Court's decision as authority for repayment, rather than relying on two statutes that do not give it that repayment authority only so that the agency can bootstrap a retrospective "budget neutrality adjustment"?

More to the point, it defies law and reason that this proposed recoupment could be made for each "year" from 2018 to 2022 when the rule authorizes a $7.8 billion recoupment in one fell swoop *in 2023*. How is this proposed recoupment being done for any particular "year" when the promulgated rule would impose a $7.8 billion "adjustment" in *a later year* (2023) to pay for five *prior years* (2018-2022)? This illogic demonstrates that HHS has no textual solution to the statute's use of the singular "the year."

It is no answer, moreover, for HHS to assert that its new reading of "the year" "is consistent with the provision that adjustments may not "'cause the estimated amount of expenditures under this part for the year to increase or decrease.'" *Id*. (quoting 42 U.S.C. § 1833(t)(9)(B)). It may be "consistent" with HHS' belief that the statute, at some general level, seeks to promote budget neutrality, but that belief is erroneous. As AHA has explained for years, HHS's belief does not account for the fact that budget neutrality is a prospective exercise, as evidenced by the word "estimated" in the statutory provision on which HHS relies. In context, the language "estimated amount … for the year" raises the exact same questions about the prospective nature of budget neutrality that HHS *still hasn't answered*. All in all, there is no textual basis for the agency's reading of "year" when it is attempt to make back-end *retrospective* clawbacks to budget neutralize errors made at the front-end of the *prospective* payment period (or, to be precise, five of them).

To put it bluntly, HHS seems more motivated by a policy desire to recoup funds from OPPS entities than anything else, and it is tying itself in knots to find the legal authority to make a "budget neutrality adjustment." But HHS is not "free to pave over bumpy statutory texts in the name of more expeditiously advancing a policy goal." *New Prime Inc. v. Oliveira*, 139 S.Ct. 532, 543 (2019); *see, e.g*., *Patel v. Garland*, 142 S.Ct. 1614, 1627 (2022) ("[P]olicy concerns cannot trump the best interpretation of the statutory text."); *Niz-Chavez v. Garland*, 141 S.Ct. 1474, 1486 (2021) ("[W]hen it comes to the policy arguments championed by the parties and the dissent alike, our points are simple: As usual, there are (at least) two sides to the policy questions before us; a rational Congress could reach the policy judgment the statutory text

To this day, including in the proposed rule, HHS has never responded to these arguments. If it is going to rely on section 1833(t)(14)(H) and its express reference to paragraph (9), it must finally do so. *See Reytblatt v. U.S. Nuclear Regulatory Comm'n*, 105 F.3d 715, 722 (D.C. Cir. 1997) ("An agency need not address every comment, but it must respond in a reasoned manner to those that raise significant problems." (citing *Action on Smoking and Health v. Civil Aeronautics Bd*., 699 F.2d 1209, 1216 (D.C. Cir. 1983))). The more likely explanation, however, is that HHS has no answer to these arguments. **By expressly invoking paragraph (9), section 1833(t)(14)(H) necessarily incorporates this prospective-only approach to budget neutrality. It therefore cannot be relied upon, as the proposed rule does, to require or authorize a corresponding *retrospective* recoupment from hospitals**. HHS therefore must look elsewhere for legal authority.[10]

The proposed rule's reliance on section 1833(t)(2)(E) for authority to repay 340B hospitals fares no better. That provision gives the HHS Secretary authority to make "other adjustments as determined to be necessary to ensure equitable payments." But that authority is to be used for discretionary payments made for equitable reasons. *See Amgen v. Smith*, 357 F.3d 103, 115 (D.C. Cir. 2004) ("Congress' amendments to § (t)(2)(E) do not mean that Congress also eliminated the Secretary's discretion to make further equitable adjustments to payment rates already adjusted through the outlier or pass-through provisions."); *see id*. at 116 (repeatedly describing the Secretary's power under section 1833(t)(2)(E) to be "flexible"). And as noted, the HHS Secretary isn't making these payments for any equitable reasons. Nor does he have any discretion here. The Secretary is making these repayments because he is *legally required* to do so following the Supreme Court's decision. Even the proposed rule recognizes this: "Because we did not use any survey of hospitals' acquisition costs, we believe it is *necessary* for the remedy to apply the default rate (generally ASP plus 6 percent) to comply with paragraph (14)(A)(iii) of section 1833(t) of the Act for those years, as interpreted by the Supreme Court." Proposed Rule at 44,083 (emphasis added).

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suggests it did; and no amount of policy-talk can overcome a plain statutory command. Our only job today is to give the law's terms their ordinary meaning and, in that small way, ensure the federal government does not exceed its statutory license."). At the end of the day, the agency should stop pretzeling itself to justify a "budget neutrality adjustment" for which is has no textual authority. The simple fact is that Congress made the decision long ago to switch from a retrospective to prospective system of payment *without* giving HHS the authority to go back and take money from hospitals and health systems that they long since spent it on patient care. The agency need not say anything more than that in the final rule (or to potential critics).

[10] The proposed rule twice mentions "the statute's general approach of budget neutralizing OPPS payment adjustments." Proposed Rule at 44,080, 44,081. But to the extent that a "general approach" exists, the proposed rule fails to recognize that it is *prospective* only.

Consequently, much like section 1833(t)(14)(H), section 1833(t)(2)(E) is an inapt provision to rely on to make the legally-required remedial repayments.

As explained in greater detail below, moreover, a repayment of this size likely cannot qualify as an "adjustment" under the text of section 1833(t)(2)(E). *See infra* 21-22 (discussing *Biden v. Nebraska*, No. 22-506, 2023 WL 4277210 (June 30, 2023)). Thus, if HHS chooses to rely on this authority for repayment only for the purpose of bootstrapping a "budget neutrality adjustment," it will put at risk the legally-required repayment to 340B hospitals. What's more, reliance on section 1833(t)(2)(E) for repayment would be futile if HHS' goal is to obtain a resultant "budget neutrality adjustment"; section 1833(t)(2)(E) is explicitly part of the *prospective* payment system ("Under the payment system"), and thus would not authorize the bootstrapped *retrospective* clawbacks. *See infra* at 18-19.

Simply put, HHS should not make this unforced error. As noted, *any* OPPS entity (including those that are not AHA members) that is injured by recoupment could attempt to invalidate the repayment if HHS wrongly insists that its authority for repayment requires a budget neutrality adjustment by tying the repayment and recoupment together. Put another way, linking the repayment and the recoupment in this manner will give every clawback victim standing to challenge the repayment, which would prolong this messy situation even longer. Indeed, all it takes is for one aggressive law firm to convince one clawback victim to bring suit, and the entire remedial scheme would be endangered. *See Am. Hospital Ass'n v. Azar*, 385 F.Supp.3d 1, 15 (D.D.C. 2019) ("Any attempt to [retrospectively recoup funds] would almost certainly trigger litigation.").[11] **The**

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[11] *See also* Katie Waldo, et al., McDermott, Will, & Emery, CMS Releases Proposed Remedy For 340B-Acquired Drugs Purchased In Cost Years 2018–2022 (July 12, 2023), *at* https://www.mcdermottplus.com/insights/cms-releases-proposed-remedy-for-340b-acquired-drugs-purchased-in-cost-years-2018-2022/ ("[C]omments will reveal whether CMS found an adequate balance, or whether dissatisfied stakeholders may be willing to challenge the remedy in court. Given how much litigation CMS and the US Department of Health and Human Services have faced over some of their recent decisions, **it would not be surprising if some aggrieved parties sued**." (emphasis added); Alex Kacik, CMS' 340B proposal a 'hard pill to swallow' for some hospitals, MODERN HEALTHCARE (July 14, 2023), *at* https://www.modernhealthcare.com/policy/340b-hospital-proposal-cms-payment-cuts-budget-neutral?utm_source=modern-healthcare-alert&utm_medium=email&utm_campaign=20230714&utm_content=hero-headline ("Budget-neutral policies are challenging since there are always winners and losers, said Michael Strazzella, senior principal of government relations at law firm Buchanan Ingersoll & Rooney. 'The fact that CMS made the proposed rule budget-neutral by reducing payments for non-drug items and services over 16 years is a hard pill for hospitals to swallow,' he said."); Nyah Phengsitthy, *HHS $9 Billion Drug Discount Fix Falls Short for Some Hospitals*, Bloomberg Law (July 11, 2023), *at* https://news.bloomberglaw.com/health-law-and-business/hhs-9-billion-drug-discount-fix-falls-short-for-some-hospitals ("'When the federal government proposes to slosh

AHA cautions HHS in the strongest possible terms not to expose itself to this consequence, which would undermine the repayment 340B hospitals are entitled to and harm the public fisc through required interest payments, additional litigation, and more.[12]

Finally, HHS' own position in the proposed rule undermines any assertion that it is absolutely *required* by statute to achieve budget neutrality. The proposed rule states that the "remedy payments are subject to budget neutrality requirements, at least when the budget neutrality adjustment would not be de minimis." *Id*. at 44,080. This means that, in HHS' view, it sometimes may not seek budget neutrality—namely, when that adjustment would be de minimis. But HHS does not—and cannot—identify any statutory text that creates this *de minimis* exception. HHS certainly does not identify any statutory language for its test for when something is *de minimis*: "When considering whether the estimated amount of expenditures is *de minimis*, we have taken into account relevant context, such as the size of the change comparable to the OPPS payments overall, the relative number of interested parties and any reliance interests, as well as the anticipated impact on the Part B Trust Fund of the change in payment due to the post-annual rulemaking policy versus the anticipated administrative burden and cost of ratesetting disruption." *Id*. at 44,081. At best, this newly-minted *de minimis* test vastly expands HHS' power to seek budget neutrality when *the agency alone* deems it proper; at worst, it is a one-time-only test, (again) reverse-engineered to obtain a recoupment here.

Strikingly, HHS' effort to give itself atextual discretion over when to seek a "budget neutrality adjustment" accords with what the agency told the district court in this case last just last fall, but strangely conflicts with assertions in the proposed rule that it is

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billions of dollars around the private sector, as HHS has here, the doors to the courthouse typically swing wide. Whichever covered hospitals believe they will get shorted if this version of the rule becomes final will be strongly incentivized to litigate,' David Slovick, an attorney at Barnes Thornburg, wrote in a statement to Bloomberg Law.").

[12] If the agency believes that its choice to rely on section 1833(t)(2)(E) can shield it from judicial review, it should think again. The agency would do well to remember that this rule is being promulgated as a remedy for legal errors that a unanimous Supreme Court identified. It is difficult to imagine courts, including the Supreme Court, countenancing another attempt by HHS to evade judicial review in this case, especially when the district court gave HHS the opportunity in the first instance to craft a legally suitable remedy. Moreover, HHS specifically asked the district court to not retain jurisdiction over the remand, arguing that it was entitled to a presumption of good faith. *See* Gov't Opp'n to Plaintiffs' Motion To Hold Unlawful And Remedy Defendants' Past Underpayment Of 340B Drugs, *Am. Hospital Ass'n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 76 at 21-22 (Sep. 14, 2022) (quoting *Empire Health Found. v. Becerra*, No. 20-2149, 2022 U.S. Dist. LEXIS 22503, at *16 (D.D.C. Feb. 8, 2022)). A later attempt to evade judicial review would call that assertion of good faith into serious question, jeopardizing all future attempts by HHS or the federal government to obtain remands without ongoing judicial supervision.

"required" to seek budget neutrality. Its district court papers stated: "Plaintiff describes three instances in which it claims the agency fixed prior errors without recouping prior payments to achieve budget neutrality. None of those instances show that the government lacks the authority to recoup payments to achieve budget neutrality, *should it choose to do so*. At most, they suggest only that the government has *some degree of discretion on the issue*." Gov't Opp'n to Plaintiffs' Motion To Hold Unlawful And Remedy Defendants' Past Underpayment Of 340B Drugs, *Am. Hospital Ass'n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 76 at 16-17. (Sep. 14, 2022). Any current assertions in the proposed rule that the agency is legally *required* to pursue budget neutrality cannot be squared with this litigation filing. HHS's cooked-up *de minimis* exception and the agency's prior briefing make one thing pellucidly clear: HHS cannot hide behind any asserted legal *requirement* to claw back resources that hospitals have long since spent, including during the COVID-19 pandemic. It is making a *choice* to do so, but that choice is wrong for a host of legal and policy reasons. Either way, it underscores that the agency's quest for budget neutrality is groundless.

C. HHS Cannot Independently Rely On Section 1833(t)(2)(E) Or Any Common Law Authority To Make a "Budget Neutrality Adjustment"

The other legal authorities on which HHS relies for its proposed "budget neutrality adjustment" also do not authorize or require the agency's proposed clawback.

For instance, the proposed rule states "even if this remedy rule were exempt from budget neutrality requirements as a matter of statutory interpretation, we would still exercise our authority under section 1833(t)(2)(E) of the Act." *Id*. at 44,082. That discretionary decision to rely on section 1833(t)(2)(E), on its own as independent statutory authority for the proposed recoupment, is unlawful.

Subsection 1833(t)(2)(E) is introduced by the text "Under the payment system," which can only refer to the *prospective* payment system addressed in section (t) as a whole. Notably, the title of section (t) is: "*Prospective Payment System* for Hospital Outpatient Department Services." This textual reference to the prospective payment system, and subsection 1833(t)(2)(E)'s inclusion within in that system, bars its use for *retrospective* recoupments for the same reasons discussed above in connection with paragraph (9) and the general purposes of the OPPS. **It would be implausible for Congress to have created a *prospective* payment system and bury within it an "adjustment" provision that independently authorizes HHS to go back and retrospectively recoup funds from all hospitals in that system**. *See supra* at 12-15 & n.8; *Georgetown Univ. Hosp.,* 821 F.2d at 759 ("[T]he Secretary has explicitly noted that he is authorized by statute to establish prospective cost-limit rules. In light of the clear congressional intent, and the uninterrupted agency practice, we are astonished that the Secretary now purports to have the authority to promulgate such rules on a retroactive basis."); *see generally Hall v. Hall*, 138 S.Ct. 1118, 1129 (2018) ("We think, moreover, that if Rule 42(a) were meant to transform consolidation into something sharply contrary to what it had been, we would have heard about it. Congress, we have held, 'does not alter the fundamental details' of an existing scheme with 'vague terms' and 'subtle

device[s].'" (quoting *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001)). Consequently, HHS cannot "exercise [its] authority under section 1833(t)(2)(E) of the Act to" *retrospectively* claw back any earlier prospective payments. Proposed Rule at 44,082.

A second textual component of section 1833(t)(2)(E) further defeats any assertion that this provision independently authorizes a recoupment. The proposed rule relies on the phrase "other adjustments as determined to be necessary to ensure equitable payments." 42 U.S.C. § 1833(t)(2)(E). But that language plainly speaks of "payments"—not clawbacks or reductions. And the surrounding statutory language supports this payment-only reading, as "outlier adjustments under paragraph (5) and transitional pass–through payments under paragraph (6)" explicitly refer to "additional payment[s]," not funding that the HHS seeks to retrospectively recoup from hospitals or even decrease during the same calendar year. *See Epic Systems Corp. v. Lewis*, 138 S.Ct. 1612, 1625 (2018) ("[W]here, as here, a more general term follows more specific terms in a list, the general term is usually understood to embrace only objects similar in nature to those objects enumerated by the preceding specific words." (quotation marks omitted)); *White Mem'l Med. Ctr. v. Schweiker*, 640 F.2d 1126, 1129 (9th Cir.1981) (relying on *ejusdem generis* in agreeing with HHS Secretary's interpretation of a statute); *Chestnut Hill Benevolent Ass'n v. Burwell*, 142 F. Supp. 3d 91, 102 (D.D.C. 2015) (same). Taken together, section 1833(t)(2)(E) is suffused with textual clues (*e.g.*, "Under the payment system, "equitable payments," and the *ejusdem generis* canon) that Congress never intended it to be used to make retrospective downward or retrospective "adjustments" like those proposed here.

Next, the NPRM states that the agency's proposal is "consistent" with "the agency's longstanding inherent and common-law (and commonsense) recoupment authority." *Id*. The AHA does not read this passage to actually rely on any common law authority to seek the proposed recoupments. If, however, the AHA is mistaken and the proposed rule is actually relying on purported common law powers (rather than merely identifying some nebulous "consistency"), HHS would be acting unlawfully.

As an initial matter, contrary to the stray suggestion in a single case cited in the proposed rule, HHS does *not* have a common law "duty" to seek recoupment. *Id*. (citing *Chaves Cnty. Home Health Serv., Inc. v. Sullivan*, 931 F.2d 914, 918 (D.C. Cir. 1991)).[13] Quite the contrary, courts have been clear that no such duty exists. *E.g.*, *Industrial Customers of Northwest Utilities v. Bonneville Power Admin*., 767 F.3d 912,

[13] The case cited in the proposed rule, *Chaves Cnty. Home Health Serv.*, does not discuss any *common law* recoupment "duty." In fact, the proposed rule only quotes part of the relevant sentence from that case. Read in full, it is clear that *Chaves Cnty. Home Health Serv.* interprets statutes that HHS does not rely on here, and not any purported inherent common law power. *See* 931 F.2d at 918 ("*These provisions* do, however, demonstrate that the Secretary generally has the duty and power to protect against overpayments to providers. (emphasis added)).

923-24 (2014) ("Certainly agencies are generally permitted to seek recovery of erroneously or illegally disbursed funds.… But that recovery authority does not suggest that the government has a constitutional duty to seek a refund every time an erroneous or illegal payment has been made."). So even if HHS could rely on this inherent power, it still would be discretionary—not required by law.

More fundamentally, no common law power of recoupment authorizes *the method* of recoupment alluded to here. Any common law authority that the government may have to recoup funds can only be exercised *by suing in court*. *See United States v. Wurts*, 303 U.S. 414, 415 (1938) ("No statute is necessary to authorize the United States to *sue in such a case*. *The right to sue* is independent of statute...." (emphasis added and quotation marks omitted) (quoted in *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 16 (1st Cir. 2005)). Critically, there is no inherent right for an agency to seek recoupment by regulation.

Agencies are creatures of statute, not the common law. "[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986); *see FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 151 (2000) ("[A]n administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress."); *Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204 (1988) ("It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress."). Thus, any reference in the proposed rule to HHS' common law authority does not permit it to engage in recoupment from 4,000+ OPPS entities by regulatory fiat. If HHS wishes to seek recoupment on a case-by-case basis, it always could try that route. But that wouldn't just be "close to impossible administratively," Proposed Rule at 44,089—it would be administratively and judicially impossible, full stop. For this reason, there is good reason for the AHA's belief that the proposed rule does not rely on or assert any common law *regulatory* recoupment powers.[14]

For all of these reasons, it is clear that HHS is not legally required—and, more importantly, not legally permitted—to pursue the proposed $7.8 billion "budget neutrality adjustment."

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[14] The AHA also does not read the proposed rule to rely on any general retroactive rulemaking authority to achieve budget neutrality. The discussion of retroactive rulemaking appears only in connection with the proposed remedial payments. *See* Proposed Rule at 44,080, 44,083-44,084. This is for good reason. As AHA has previously explained, HHS cannot rely on any general retroactive rulemaking statutes to claw back funds, because, *inter alia*, it would still need to rely on paragraph (9), which itself is prospective only. *See* Reply In Support Of Plaintiffs' Motion to Hold Unlawful And Remedy Defendants' Past Underpayment of 340b Drugs, *Am. Hospital Ass'n v. Becerra*, Case No. 1:18-cv-2084, Dkt. 78 at 14-17 (Sep. 21, 20222).

D. HHS May Not Seek A $7.8 Billion Budget Neutrality "Adjustment"

HHS proposes to recoup $7.8 billion from all OPPS hospitals and health systems, in whole or in part based on section 1833(t)(2)(E)'s authority to make "other adjustments." In fact, the word "adjustment" appears *more than 100 times* in the proposed rule. But a recoupment of this size, scope, and nature cannot qualify as an "adjustment" within the meaning of section 1833(t)(2)(E). Thus, if the agency chooses to seek a budget neutrality "adjustment" at all, it cannot seek the one it has proposed.

In 2018, the district court in this case correctly explained: "While the Secretary is permitted to make 'adjust[ments]' … for whatever reasons he deems 'necessary,' adjustments are all he can make." *Am. Hospital Ass'n v. Azar*, 348 F.Supp.3d 62, 82 (D.D.C. 2018). Put another way, if a purported "adjustment" is "sufficiently large," it ceases to be an adjustment. *Id*. at 82 n. 16.

The Supreme Court's recent decision in *Biden v. Nebraska* bolsters this reading of the word "adjustment." It is important to bear in mind that the D.C. Circuit has interpreted HHS' "adjustment" authority to have the same limits that the Supreme Court has found in the word "modify." *See Amgen*, 357 F.3d at 117. And less than two months ago, the Supreme Court held that "the term 'modify' carries a connotation of increment or limitation, and must be read to mean "to change moderately or in minor fashion." *Biden v. Nebraska*, No. 22-506, Slip. Op. at 13; *id*. ("The legal definition is no different. Black's Law Dictionary 1203 (11th ed. 2019) (giving the first definition of 'modify' as '[t]o make somewhat different; to make small changes to,' and the second as '[t]o make more moderate or less sweeping')"). As such, any "adjustment" under section 1833(t)(2)(E) must be moderate and not too large or sweeping.

Given this more recent Supreme Court decision, moreover, HHS cannot rely on the D.C. Circuit's opinion in this case, which misread the term "adjustment" to apply to changes that are more than minor. That majority opinion, which itself was overturned on other grounds by the Supreme Court, incorrectly stated: "But we do not read *Amgen* to prescribe that 'adjust' in the OPPS statute refers only to minor changes." *Am. Hospital Ass'n v. Azar*, 967 F.3d 818, 833-34 (D.C. Cir. 2020). But as Judge Pillard wisely explained in her dissent years ago:

> The Hospitals' limited reading of the adjustment authority that subclause (II) confers is supported by our previous caution that the term 'adjustment' in this statute—like the term 'modify' at issue in *MCI Telecommunications Corp. v. AT&T Co*., 512 U.S. 218, 225 (1994), which the Court held 'means to change moderately or in minor fashion'—cannot permit 'basic and fundamental changes in the scheme.' *Amgen, Inc. v. Smith* 357 F.3d 103, 117 (D.C. Cir. 2004) (quoting *MCI* , 512 U.S. at 225). The majority distinguishes *Amgen* by quoting our observation there that we had 'no occasion to engage in line drawing to determine when 'adjustments' cease being 'adjustments.'' *Id*. But that observation made eminent sense in a

> dispute 'involving only the payment amount for a single drug,' and we went on to warn that a 'more substantial departure from the default amounts would, at some point, violate the Secretary's obligation to make such payments and cease to be an 'adjustment.'' *Id*. (alteration omitted). Given the scale and segmentation of the rate cut at issue—reducing SCOD reimbursements by nearly a third, thereby eliminating $1.6 billion annually in reimbursements to many of the most financially vulnerable hospitals in the Medicare program—I disagree that, '[e]ven if there are limits to what HHS could permissibly consider an 'adjustment,' that line has not been crossed here.'

Id. at 838 (Pillard, J. dissenting). Thus, the Supreme Court not only vindicated Judge Pillard's position when it decided *American Hospital Association v. Becerra*, it further vindicated it a year later when deciding *Biden v. Nebraska*. Based on that decision and the persuasive reasoning in Judge Pillard's dissent, "adjustment" must be read as authorizing only *minor* changes.

The proposed $7.8 billion recoupment does not satisfy this statutory definition of "adjustment" for several reasons.

First, its sheer size is, in itself, fatal. Needless to say, an overall $7.8 billion recoupment is a substantial amount of money that far exceeds any reasonable understanding of "adjustment." Considered another way, if $7.8 billion is not a sufficiently large amount of money to exceed the definition of "adjustment," then the Trust Fund would have far less "interest in recovering" it, *see* Proposed Rule at 44,082, or it would meet the agency's aforementioned *de minimis* budget neutrality test, *see id*. at 44,081 (listing "size of the change comparable to the OPPS payments overall, the relative number of interested parties …, as well as the anticipated impact on the Part B Trust Fund" as factors for determining whether budget neutrality offsets are required).

Second, while this $7.8 billion is spread across all entities participating in the OPPS, that only makes matters worse for the lawfulness of this proposal. This proposed recoupment will impact thousands of covered entities. That can only be described as sweeping in scope. And that, too, dooms the proposal. *See Am. Hospital Ass'n v. Azar*, 348 F.Supp.3d at 81 ("The Secretary's rate adjustment at issue here does not affect a single drug or even a handful of drugs, but rather potentially thousands of pharmaceutical products found in the 340B Program."); *see also Am. Hospital Ass'n*, 967 F.3d at 838 (Pillard, J., dissenting) (relying, in part, on the fact that HHS' prior policy affected more than a single drug as reason why it was not an "adjustment"). HHS, moreover, has not identified any prior "adjustment" as sweeping as the one proposed here. *See Nebraska*, No. 22-506, Slip. Op. at 13 ("The Secretary's previous invocations of the HEROES Act illustrate this point."). Further, because this proposed recoupment impacts *all* hospitals in the OPPS, it raises additional legal questions under the text of section 1833(t)(2)(E). Although that provision authorizes "other adjustments as determined to be necessary to ensure equitable payments," the only example expressly

provided by the statute is "adjustments for *certain classes* of hospitals." It is not clear, then, that section 1833(t)(2)(E) can be used as a backdoor authority to change rates for *all* OPPS entities, rather than for "certain classes" of them.[15]

Third, the retrospective nature of this proposed "adjustment" constitutes a serious change to the OPPS scheme. As noted, the OPPS scheme is *prospective*. *See supra* at 12-15 & n.8 (noting Congress' intentional decision to create a prospective payment system and citing cases describing the difference between a prospective and retrospective payment system); *supra* at 18-19 (discussing the textual reference in section 1883(t)(2)(E) to "Under the payment system"). Allowing HHS to retrospectively "adjust" payment rates and conversion factors, years after those payments were made, fundamentally restructures the *prospective* system that Congress intentionally designed. "It is highly unlikely that Congress authorized" HHS to completely invert the *prospective* payment system, allowing it to *retrospectively* claw back funds from all OPPS participants "through such a subtle device as permission to" adjust. *Nebraska*, No. 22-506, Slip. Op. at 15 (internal quotation marks omitted).

Taken together, these factors make the proposed $7.8 billion "adjustment" anything but "'moderate' or 'minor.'" *Id*. at 14.[16] If HHS chooses to pursue any recoupment at all—and it should not—then it must drastically reduce or modify its proposal in the final rule to better align with the "minor" adjustments permitted by statute. Not only would that better ground the proposal in the text of section 1833(t)(2)(E), but it would reduce the risk of thousands of individual lawsuits from OPPS entities (including some who are not AHA members), who will have funding clawed back years after they spent it on patient care.

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[15] This is in marked contrast to the agency's proposed exercise of its "adjustment" authority to repay beneficiary cost-sharing. There, at least, only a subset of hospitals would be subject to this adjustment. And that "adjustment" is a payment, not a reduction or clawback. *See* 42 U.S.C. § 1833(t)(2)(E) ("other adjustments as determined to be necessary to ensure equitable *payments*" (emphasis added). And it is manifestly "equitable" because it spares patients from having to make co-pays years after they received medical services.

[16] By contrast, the proposed exercise of "adjustment" authority to pay 340B hospitals what they would have obtained in cost-sharing payments is on more solid legal footing. It is far smaller than $7.8 billion, applies only to a "certain class" of hospitals (*i.e.*, 340B hospitals that suffered from the agency's own mistakes), and is a payment that hospitals would have received prospectively but for the HHS' unlawful reductions rather than an attempt to retrospectively recoup prior payments. Critically, moreover, any exercise of authority under section 1833(t)(2)(e) for cost-sharing payments is untethered to the bulk of the remedial payments, which does not subject it to the litigation risks discussed above (at 16 n.11) if repayment and recoupment are linked. Accordingly, this proposed exercise of section 1833(2)(e) authority as a payment to hospitals is supportable and, as noted above, should be finalized.

E. HHS' Policy Justifications Do Not Support The Proposed $7.8 Billion "Adjustment"

HHS states that a "budget neutrality adjustment is … warranted as a matter of sound public policy." It is not.

Before explaining why, it is important to highlight the serious public policy concern that HHS *nowhere* addresses in its proposed rule: the state of hospital finances, which will continue suffer because of systemically inadequate Medicare reimbursement. On average, Medicare pays 84 cents for every dollar of care provided, which has led to Medicare margins for outpatient care for all hospitals to be -17.5% in 2021. **Clawing back funds from hospitals and health systems would constitute a conscious choice by the Administration to make a Medicare cut that further depresses these margins, creating additional financial challenges for hospitals and health systems across the country.**

This Medicare cut would harm all hospitals subject to it, but it will have significant harmful impacts on specific classes of hospitals that can scarcely afford it. For instance:

- Rural hospitals will have to return more than $900 million to the government, despite their precarious financial state and HHS' express acknowledgment that the clawback will be "financially burdensome" to them. Proposed Rule at 44,087. The latest data from the UNC Sheps Center shows that 152 rural hospitals have closed or converted to another provider type since 2010, with 11 occurring so far in 2023. Another 600 rural hospitals report that they are on the brink of closing their doors. The agency's clawback proposal will risk more rural hospital closures—a reality that would eviscerate access to care for the 60 million Americans that live in rural areas.

- Rural sole community hospitals alone will have to pay back more than $600 million, even though HHS intentionally exempted them from its prior policy for sound policy reasons.

- Cancer hospitals, which were also previously exempted from HHS' unlawful policy for sensible policy reasons, will have to return more than $100 million to the government. This will jeopardize access to care for cancer patients who rely on these hospitals for specialized care.

In deciding whether to make these "budget neutrality adjustments," we urge HHS to take into account this important public policy consideration.

Turning to HHS' own public policy contentions, the proposed rule proffers a single explanation for why HHS believes it should pursue recoupment here—namely, that the funds it seeks to claw back from hospitals and health systems "have proven to be an

unwarranted windfall, and the Trust Fund has a strong interest in recovering them." Both parts of this statement—before and after the comma—are wrong.

HHS' assertion that these funds would constitute a "windfall" is incorrect and reflects a disturbing lack of humility on the agency's part. **Shockingly, HHS fails to acknowledge that hospitals had *no choice* but to accept this funding because *HHS itself* made serious legal errors over the course of five years that the Supreme Court unanimously invalidated. Even worse, in repeatedly using the word "windfall," HHS nowhere accepts responsibility for *its own* role in creating this situation.** Critically, it was HHS that instituted an illegal policy, and it was HHS that continued to defend and implement that policy year after year, even when a district court found it to be unlawful. Under the OPPS system, hospitals could not have refused that funding even if they tried. Now, however, years after these hospitals spent these funds—including to care for patients during a once-in-a-century pandemic—HHS seemingly tries to chasten them for doing so. Ultimately, we all are in "these truly unique circumstances," as the proposed rule calls it (at 44,089), entirely because of *HHS'* unlawful actions, and the agency must face up to its role in causing this situation. Before finalizing any rule based on the sentiment that "we *must* find a means of recovering this windfall," *see* Proposed Rule at 44,086, the AHA respectfully asks HHS to seriously consider its role in any asserted "windfall" and whether hospitals should be adversely impacted in the future for the agency's own unlawful actions in the past.[17]

Next, the proposed rule's reference to any interest that the Trust Fund may have in recoupment is overstated. As the proposed rule notes, the Trust Fund at issue here is the Supplementary Medicare Insurance (SMI) Trust Fund. *See* Proposed Rule at 44,081. But the proposed rule's discussion of the most recent *Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medicare Insurance Trust Funds* leaves out the report's topline conclusion: "The SMI trust fund is expected to be adequately financed over the next 10 years *and beyond*… Financing for the SMI trust fund is adequate because beneficiary premiums and government contributions, for both Part B and Part D, are established annually to cover the expected costs for the upcoming year." The Boards of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2023 ANNUAL REPORT OF THE BOARDS OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICARE INSURANCE TRUST FUNDS 10, 39 (hereinafter "2023 TRUST FUND REPORT") (emphasis added), *at* https://www.cms.gov/oact/tr/2023; *see id*. at 44 ("The financial outlook for SMI is fundamentally different than for HI [hospital insurance trust fund] as a result of the statutory differences in the methods of financing for these

[17] As noted below (at 28-30), moreover, the only entities that will receive a "windfall" are the Medicare Advantage Organizations (MAOs) that reduce their payment rates to hospitals if HHS seeks to recoup funds by reducing traditional Medicare payment rates without any corresponding requirement to pass on the savings back to the hospitals whose payments the MAOs cut in connection with the agency's unlawful policy.

two components of Medicare."). Put another way, while there may be some risk that significant unexpected increases in Part B expenditures could have adverse impact on the trust fund, *see* Proposed Rule at 44,081, there is no risk that the SMI Trust Fund will become insolvent in the foreseeable future. And there is no indication whatsoever that the $7.8 billion in question here is the kind of "significant unexpected increase" that the Trustees' report was referring to.

To be clear: The AHA is always concerned about the long-term viability of the Medicare trust funds, and it continues to urge policymakers to shore up their futures. But the SMI Trust Fund is fundamentally different from the Part A trust fund in that it is projected to remain solvent and recent projections actually indicate lower anticipated expenditures over time due to a variety of factors, including the passage of the Inflation Reduction Act. *See* 2023 TRUST FUND REPORT 45. And perhaps more important, even if the proposed rule is correct that "unexpected increases in Medicare Part B or D expenditures could require tax increases or expenditure reductions elsewhere in the Federal budget," the amounts at issue here (at most, $7.8 billion in recoupment) are exceptionally small as compared to the overall federal budget, especially when spread out over 16 years.

Finally, in expressing its concern for the Trust Fund, the proposed rule states that achieving budget neutrality serves an "important interest" in "protecting the public fisc." Proposed Rule at 44,081. **But allowing HHS to pursue retrospective budget neutrality actually *increases* risks for the public fisc**. Rather than forcing HHS and the Department of Justice to be disciplined on the front-end when crafting policies and legal arguments to support those policies, allowing them to make up for their mistakes via recoupment discourages that necessary rigor and balancing of litigation risk. **Indeed, if HHS knows that it can simply claw back funds in the future, then it will be more likely to take aggressive or unsupported positions at the outset.**

This case is the perfect example of this moral hazard problem. Because HHS (wrongly) believed it could pursue retrospective budget neutrality, it persisted in years of unlawful policies and needless litigation, raising costs for the federal fisc. If HHS had been told years ago that it could not recoup funds from hospitals to make up for its unlawful cuts, one wonders whether the agency would have continued to implement its illegal policy? **Forgoing recoupment therefore promotes the important public policy goal of responsible stewardship of both the Trust Fund and the federal fisc.**

F. The Final Rule Should Contain No "Budget Neutrality Adjustment" Or, At The Very Least, A Substantially Reduced "Adjustment"

For the reasons stated above, the legal and public policy reasons that HHS offers in its proposed rule do not support its $7.8 billion "adjustment." **Accordingly, HHS must eliminate or, at the very least, substantially reduce that amount in its final rule.**

As noted, the proposed rule does not identify a viable legal authority for any "budget neutrality adjustment." The cited statutory provisions (sections 1833(t)(2)(E) and 1833(t)(14)) and allusions to the common law do not authorize the clawback proposed here. Nor do the asserted public policy reasons justify it. **HHS should not seek any "budget neutrality adjustment" at all**.

If HHS disagrees, it must seek a drastically reduced "adjustment." As noted, a retrospective $7.8 billion clawback from all OPPS hospitals is not an "adjustment" under the statute and Supreme Court precedent. Should HHS nonetheless assume the considerable legal risk and pursue an "adjustment" at all, the AHA offers two proposals for how HHS could best reduce the proposed $7.8 billion amount in what HHS calls (at 44,081, 44,082, 44,085, 44,087, 44,088, 44,089) these "unique circumstances":

1) Apart from no recoupment at all, the safest approach would be to implement payment reductions of only **$1.8 billion** to offset HHS' lawful exercise of authority under section 1833(t)(2)(E) to pay the cost-sharing portion of the repayments. An "adjustment" of this size is more likely to survive review in the potentially thousands of individual cases hospitals could bring because it is commensurate with the amounts HHS will be paying as a siloed part of its remedy. While this "adjustment" would still share some of the legal problems associated with a retrospective exercise of section(t)(2)(E) authority for all hospitals, an equal offsetting amount would reduce the likelihood of challenge, substantive litigation risk, and attendant costs to the public fisc.

2) At the very least, the "adjustment" amount should **exclude CYs 2020-2022**. During those years, hospitals struggled with a once-in-a-century pandemic in ways the AHA need not recount here. Suffice it to say, however, that any alleged "windfall" that hospitals may have received during those years was well spent on critical work to keep patients and communities safe and healthy from COVID-19. As President Biden has said, "Our doctors, nurses, hospital staffs have gone above and beyond during this pandemic. The strain and stress is real. I really mean it. It's real. And we'll have their backs though. We have to let them know we have their backs." Remarks by President Biden on the Fight Against COVID-19 (Dec. 21, 2021), *at* https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/12/21/remarks-by-president-biden-on-the-fight-against-covid-19/. Taking back funds spent during the pandemic years would be inconsistent with this Presidential promise. What's more, hospitals struggled financially those years, making the claim that they benefited from a "windfall" even more specious. **Thus, to the extent that HHS would be exercising its section 1833(t)(2)(e) authority (in whole or in part) to make an "equitable" adjustment for this clawback, it would be profoundly inequitable to recoup funds for the COVID-19 years**. As such, HHS can and should, at a minimum, reduce its proposed "adjustment" to better align with basic principles of equity by excluding CYs 2020-2022.

Make no mistake, these two options should be considered *only if* HHS incorrectly concludes it has legal authority to make a recoupment at all. For the many reasons explained throughout this comment letter, it *does not* have that authority. Any conclusion otherwise would invite extraordinary litigation risk from 4,000+ OPPS entities. But if HHS is willing to assume this risk, defy the statutory text in a variety of ways, and still pursue a clawback, then it must consider these more "moderate" adjustments in light of *Biden v. Nebraska* and commonsense equitable principles.

With all of this mind, the AHA also wishes to respond to two specific questions that the proposed rule asked about how to effectuate a "budget neutrality adjustment," if HHS wrongly chooses to pursue one at all.

The proposed rule asked whether the proposed "adjustments" should begin in 2025 or 2026. **HHS should delay the start of any "adjustments" until 2026 at the earliest**. Hospitals still feel the financial effects of COVID-19. As America's hospitals and health systems struggle to dig out of the pandemic, their margins remain below historical norms. *See* Kaufman Hall, NATIONAL HOSPITAL FLASH REPORT: JUNE 2023, *at* https://www.kaufmanhall.com/sites/default/files/2023-06/National-Hospital-Flash-Report_June-2023.pdf. And as the *Wall Street Journal* recently reported:

> Distressed hospitals are reporting they don't have enough cash to satisfy lenders, which typically require borrowers to meet periodic profit and other financial targets. Lenders are demanding that hospitals hire consultants to help turn around their operations or set aside cash for repayment. Failures to meet such obligations to lenders can technically count as default, putting hospitals at risk of credit downgrades and higher interest rates.
>
> To avoid that fate, hospitals are closing or scaling back unprofitable services, selling assets or cutting pay, temporary staff and jobs, according to hospital disclosures, credit analysts and financial advisers. Some have refinanced debt, submitting to today's higher interest rates in exchange for new loan terms.

Heather Gillers and Melanie Evans, *Some Hospitals That Spent Big on Nurses During Pandemic Are Now Short on Cash*, WALL STREET JOURNAL (July 5, 2023), *at* https://www.wsj.com/articles/some-hospitals-that-spent-big-on-nurses-during-pandemic-are-now-short-on-cash-d20f0435.

Given these ongoing financial realities, *any* delay in imposing the proposed "adjustment" will provide important relief to hospitals, allowing them to further recuperate from the financial impacts of the COVID-19 pandemic. Starting an "adjustment" in 2026 or later achieves this imperative.

Finally, the proposed rule asks for comment on ways to effectuate a recoupment other than a 0.5% reduction in the conversion rate (*e.g.*, a fixed dollar amount across 16 years). *See* Proposed Rule at 44,089. This question spotlights a significant problem with

any recoupment, albeit one that the agency does not appear to have contemplated in its proposed rule. Specifically, many commercial Medicare Advantage Organizations (MAO) pay hospitals according to the traditional Medicare payment rates. As such, there is a significant risk that these commercial MAOs will pay hospitals a decreased rate because of HHS' recoupment methodology. This would *double* the adverse impact of the proposed recoupment on hospitals. And this problem will only increase throughout the 16 year repayment period if Medicare Advantage continues to grow, as it is expected to do (*e.g.*, the Congressional Budget Office anticipates MA enrollment growing to approximately 60% vis-à-vis traditional Medicare enrollment by 2032).

To make matters worse, these MAOs—and not the federal government—will receive a windfall from the government's effort to recoup funds, *especially if the MAOs continue to refuse to pay the difference between the unlawful 340B policy amounts and what hospitals are owed*. *See supra* 7 n.4. Put another way, instead of the SMI Trust Fund receiving this 0.5% from the Medicare Advantage population, it will go directly into the pockets of commercial MAOs whose profits are already skyrocketing. This would contradict the primary public policy justification offered in the proposed rule.

This MAO-related defect underscores the many pitfalls and inequities in seeking a retrospective clawback to account for HHS' past mistakes. If HHS nonetheless makes the misguided decision to seek a recoupment, it must consider this complication and craft an appropriate recoupment methodology so that hospitals are not further punished by this MAO double-dipping. **Whether it is lowering the overall "adjustment" amount to account for this MAO windfall or to finding a way to recoup funds that forecloses that windfall, <u>such as achieving recoupment through a cost report reconciliation rather than through the payment rate or PRICER</u>, HHS cannot ignore this problem in the final rule**.

*** * * ***

<u>In sum, HHS should not pursue any "budget neutrality adjustment." If it does, it should 1) drastically reduce the overall amount; 2) delay any recoupment until 2026 or later; 3) finalize the current aspect of the proposal that would spread the "adjustment" across 16 years (or more)[18]; and 4) recoup funds in a way that does</u>

[18] There appears to be a consequential discrepancy in the agency's total OPPS payments data on which HHS would apply the 0.5% proposed reduction to the OPPS conversion factor in its proposed "budget neutrality adjustment." Specifically, in the FY2024 OPPS Proposed Rule, the agency states that total OPPS payments were $88.6 billion, whereas the OPPS impact file for this proposed rule states that OPPS payments for all providers total $65.65 billion. We recognize that some of the difference may be due to expected changes in enrollment and case mix, but that would only be responsible for a small portion of the difference. Ultimately, this $23 billion discrepancy in the base amount is extremely concerning, as the impact to individual

not lead to a MAO windfall at the expense of hospitals and health systems, which in no way benefits the SMI Trust Fund.

III. CONCLUSION

After years of litigation and multiple rulemakings, the process of correcting HHS' unlawful 340B policy is finally approaching the finish line. The AHA is grateful for HHS' attentive proposals for how to repay 340B hospitals fully, promptly, and with the least administrative burden. It encourages the agency to finalize those aspects of the proposal. By contrast, HHS' proposed "budget neutrality adjustment" suffers from a host of legal and public policy defects. That proposal must not be finalized at all, and certainly not at the $7.8 billion figure discussed in the NPRM.

We appreciate your consideration of these issues. Please contact me or Chad Golder, deputy general counsel, at cgolder@aha.org, if you have questions.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel and Secretary

OPPS hospitals and the 16-year estimated recoupment period would change significantly depending on which base number is correct. **The fact that there is a discrepancy across CMS' numbers is yet another reason why HHS must abandon its clawback proposal altogether. The agency's apparent inability to correctly calculate how long it will take to recoup funds creates a troubling level of uncertainty for stakeholders. After all, if the agency's own predictions are off by so much, how can it expect hospitals and health systems to accurately financially plan for the future?** At a minimum, should the agency choose to pursue a "budget neutrality adjustment" at all, it should clarify the base amount upon which the reduction will be applied and must guarantee that the "adjustment" timeline is no less than 16 years, even if that means it needs to adjust the annual amount it intends to claw back.