

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL  
ASSOCIATION,  
*et al.*,

*Plaintiffs,*

—v—

XAVIER BECERRA, in his official capacity as  
the Secretary of Health and Human Services, *et*  
*al.*,

*Defendants.*

Civil Action No. 18-2084 (RC)

**MOTION TO HOLD UNLAWFUL AND REMEDY  
DEFENDANTS' PAST UNDERPAYMENT OF 340B DRUGS**

The Supreme Court has now unanimously held that Defendants violated their statutory obligations when they drastically cut Medicare drug reimbursement rates for 340B hospitals in the 2018 and 2019 OPPS Rules. *Am. Hosp. Ass'n v. Becerra*, 124 S. Ct. 1896 (2022). The Court ruled that “absent a survey of hospitals’ acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals” relative to other hospitals, and “HHS’s 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.” *Id.* at \*8. Consistent with the Supreme Court’s ruling, Plaintiffs hereby ask the Court to hold unlawful the 2020, 2021, and 2022 OPPS Rules, each of which continued the same unlawful policy of paying much less for the same drugs if they were acquired under the 340B Program.<sup>1</sup>

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<sup>1</sup> Plaintiffs have filed an unopposed Motion for Permission to File Second Supplemental Complaint, which would add challenges to the 2020, 2021, and 2022 OPPS Rules to this case. ECF 66. Plaintiffs also have filed a motion that asks the Court to hold the 2022 OPPS Rule unlawful and to forbid Defendants from underpaying for 340B drugs for the remainder of 2022. ECF 67. The Court need only determine the lawfulness of the 2022 OPPS Rule once.

With respect to remedy, Plaintiffs ask the Court to order Defendants to promptly correct their past underpayments to Plaintiffs and their members for 2018–2022. Although the Court previously decided to remand the case for CMS to consider possible remedies, the situation has changed considerably following the Supreme Court’s decision. Now, there is only one available remedy: repaying those hospitals that were unlawfully underpaid, from 2018 to the present, the difference between what they were paid and ASP plus 6%. Moreover, any potential arguments about the need for budget neutrality lack merit given the text of statute, Defendants’ past practice, and basic equitable principles. For these reasons, the Court should order Defendants to swiftly correct five years of their own mistakes. Plaintiffs respectfully request that this Court issue such an order as soon as practicable.

### **BACKGROUND**

As the Court is aware, Plaintiffs challenged Defendants’ 2018 and 2019 regulations that cut Medicare reimbursements for drugs acquired under the 340B Program from ASP plus 6% to ASP minus 22.5%. The Supreme Court has now held that, “absent a survey of hospitals’ acquisition costs, HHS may not vary the reimbursement rates for 340B hospitals” relative to other hospitals, and “HHS’s 2018 and 2019 reimbursement rates for 340B hospitals were therefore contrary to the statute and unlawful.” *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. 1896, \*8 (2022).

While this case was on appeal (and thus not within this Court’s jurisdiction), Defendants issued OPPS Rules for 2020, 2021, and 2022, in which they continued their policy of reimbursing drugs acquired under the 340B Program at the significantly reduced rate of ASP minus 22.5%. *See* 2020 OPPS Rule, 84 Fed. Reg. 61,142, 61,324 (Nov. 12, 2019); 2021 OPPS Rule, 85 Fed. Reg. 85,866, 86,053–54 (Dec. 29, 2020); 2022 OPPS Rule, 86 Fed. Reg. 63,458, 63,648 (Nov. 16, 2021). For all three years, Defendants continued to reimburse the very same, separately payable

drugs at a rate of ASP plus 6% when *not* acquired under the 340B Program. *See* 2020 OPSS Rule, 84 Fed. Reg. at 61,317; 2021 OPSS Rule, 85 Fed. Reg. at 86,038–39; 2022 OPSS Rule, 86 Fed. Reg. at 63,640–41.

Defendants continued this policy of varying reimbursement rates for 340B hospitals even though they never attempted to justify the reduced rate of ASP minus 22.5% using the acquisition cost survey data that the statute requires.<sup>2</sup> Rather, they continued to justify the lower payment rate for 340B hospitals by invoking their authority under “subparagraph (II)” of the statute, which applies “if hospital acquisition cost data are not available.” 42 U.S.C. § 1395l(t)(14)(A)(iii)(II); *see* 2020 OPSS Rule, 84 Fed. Reg. at 61,317, 61,324–25 (finalizing proposal to reimburse 340B drugs at ASP minus 22.5%, without any reference to survey data); 2021 OPSS Rule, 85 Fed. Reg. at 86,052 (invoking subparagraph (II) authority as basis for reduced reimbursement rate for 340B drugs); 2022 OPSS Rule, 86 Fed. Reg. at 63,646 (same). This is the very policy that the Supreme Court has now held unlawful. *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. at \*8.

On July 15, 2022, in the proposed 2023 OPSS Rule, Defendants announced that, “in light of the Supreme Court’s decision in *American Hospital Association*, we fully anticipate reverting to our prior policy of paying ASP+6 percent regardless of whether a drug was acquired through the 340B program” for 2023. CMS, 2023 OPSS Proposed Rule, 87 Fed. Reg. 44,502, 44,648 (July 26, 2022). However, with respect to remedying their past unlawful underpayments, Defendants stated only that they “are still evaluating how to apply the Supreme Court’s recent decision to cost years 2018-2022.” *Id.* at 44,649.

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<sup>2</sup> CMS did conduct a survey in 2020, but CMS never relied on the survey in setting a reimbursement rate of ASP minus 22.5% for 340B drugs, and in any event the survey did not comply with the requirements of 42 U.S.C. § 1395l(t)(14)(D), as several commenters pointed out. *See* 2021 OPSS Rule, 85 Fed. Reg. at 86,050–52.

## ARGUMENT

### **I. The Court Should Hold Unlawful Defendants’ Policy of Underpaying for 340B Drugs Pursuant to the 2020, 2021, and 2022 OPPS Rules.**

The Court should hold the 2020, 2021, and 2022 OPPS Rules unlawful, just as it and the Supreme Court did for the 2018 and 2019 OPPS Rules. Because in 2020, 2021, and 2022 Defendants paid less for 340B drugs without resting their reimbursement policy on the statutorily-required survey data, their “[2020, 2021, and 2022] reimbursement rates for 340B hospitals were . . . contrary to the statute and unlawful.” *Am. Hosp. Ass’n*, 142 S. Ct. 1896, at \*8.

### **II. The Court Should Order Defendants to Correct Their Underpayments for 340B Drugs Under the 2018–2022 OPPS Rules.**

Plaintiffs further ask the Court to order Defendants to reimburse all 340B hospitals—including the Hospital Plaintiffs and the hospital members of the Association Plaintiffs—for their underpayments on all 340B-acquired drugs from 2018 to 2022. Plaintiffs recognize that the Court previously decided to remand this case to CMS for an initial determination of a remedy. But the rationale for the Supreme Court’s ruling has changed the landscape and now makes it most appropriate for this Court to order Defendants to promptly remedy their violations of the statute.

#### **A. After the Supreme Court’s decision, Defendants’ only remedial option is to make up the difference between what they paid and ASP plus 6%, and the Court should order them to do so.**

The Supreme Court’s rationale for invalidating the 2018 and 2019 OPPS Rules differed from the rationale relied on by this Court, and that difference dictates a single possible remedy. The *only* way for Defendants to fix the statutory violation that the Supreme Court identified is to promptly pay 340B hospitals the difference between the amounts previously paid for 340B drugs and ASP plus 6%. This Court can and should order Defendants to do so promptly.

When this Court ruled against Defendants in 2018 and 2019, it held that the challenged rate reductions were unlawful because they exceeded CMS’s authority to “adjust” rates under 42 U.S.C. § 1395l(t)(14)(A)(iii)(II). *See* Order, ECF 25 at 23–30. Under that rationale, CMS argued that it had authority to make another attempt a “adjusting” payment rates for 340B hospitals downward from the 2017 rate of ASP plus 6% (for example, to ASP plus 3%), and should therefore be given a chance to do so. *See, e.g.*, ECF 36 at 5–6 (government arguing, prior to the Supreme Court’s ruling, that this Court should not order any specific remedy given that “there is more than one remedial option available to the Agency”).<sup>3</sup>

The Supreme Court, however, invalidated the rate reductions for 2018 and 2019 for a different reason—namely that that “the statute does not grant HHS authority to vary the reimbursement rates by hospital group.” *Am. Hosp. Ass’n v. Becerra*, 142 S. Ct. 1896, at \*12. The 2018 and 2019 OPPS Rules that were before the Supreme Court did just that: both Rules varied the payment rates for the same drugs depending on whether they were acquired by 340B hospitals.

This alternate rationale effectively dictates what CMS must do to fix its violation. Under the Supreme Court’s reasoning, there is no possibility for Defendants to go back and readjust their rates downward from ASP plus 6% for 340B hospitals. Instead, having failed to conduct the required survey, CMS must now reimburse 340B drugs each year at *the same* rate used for non-340B drugs that year. For every year from 2018 through 2022, CMS has *already decided* the payment rate for non-340B drugs: ASP plus 6%. CMS has no choice but to match that rate for 340B drugs. That is the *only* way to rectify the particular statutory violation that the Supreme Court

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<sup>3</sup> CMS later sought public comment on “whether a rate of ASP+3 percent could be an appropriate remedial payment amount . . . for purposes of determining the remedy for CYs 2018 and 2019.” *See* Proposed 2020 OPPS Rule, 84 Fed. Reg. 39,398, 39,504 (Aug. 9, 2019).

identified. Defendants appear to agree. *See* 2023 OPSS Proposed Rule, 87 Fed. Reg. at 44,647 (“We fully anticipate applying a rate of ASP+6 percent to [340B drugs] in the final rule for CY 2023, in light of the Supreme Court’s recent decision.”). Given all of this, the Court should order Defendants to promptly repay 340B hospitals the difference between what they were previously paid and ASP plus 6%.<sup>4</sup>

Defendants may nonetheless ask the Court to allow them to craft a proposed remedy in the first instance and likely will point to their request for comment in the recently issued proposed 2023 OPSS Rule. In that proposed rule, Defendants stated that they “are still evaluating how to apply the Supreme Court’s recent decision to cost years 2018-2022,” and they solicited “public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022.” 2023 OPSS Proposed Rule, 87 Fed. Reg. at 44,649. Defendants’ request for comment is notable for what it did *not* include: a firm commitment to repay 340B hospitals the difference between what they were paid and ASP plus 6% for 2018 through 2022. It would be one thing if Defendants had announced their intention to fully rectify their unlawful underpayments and solicited comments only on exactly how to do so. But instead, Defendants referenced “any proposed, *potential* remedies affecting calendar years 2018-2022.” *Id.* (emphasis added). Even if Defendants can solicit comments and make a policy decision regarding “how best to craft” the remedy, the Court should issue an order leaving them no discretion regarding what remedy they must accomplish: prompt and full repayment of the difference between what 340B hospitals were paid and ASP plus 6%.

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<sup>4</sup> Such an order would be consistent with Defendants’ statements in the initial case challenging the 2018 OPSS Rule, where they acknowledged that if Plaintiffs were to ultimately prevail, they could obtain “an order directing Defendants to reinstate the ASP+6% OPSS payment rate for 340B drugs.” *Am. Hosp. Ass’n v. Hargan*, No. 17-2447, ECF No. 18 at 49 (D.D.C., filed Dec. 1, 2017).

**B. Budget neutrality should not impede the Court from ordering Defendants to correct their past underpayments.**

Defendants have previously invoked “budget neutrality” to argue that any court-ordered remedy would disrupt the OPSS by forcing CMS to retrospectively recoup payments from other providers, and thus that Defendants should be permitted to decide on a remedy themselves. *See* ECF 31 at 9–10; ECF 36 at 9. This argument is doubly mistaken.

As an initial matter, Defendants’ appeal to budget neutrality fails because it mistakes *whether* the government should fix its unlawful underpayments with the questions of *how* and *when* it should do so. It is clear from the Supreme Court’s unanimous decision that Defendants’ must pay 340B hospitals for the unlawful reimbursement cuts and that those hospitals must be repaid the difference between what they were paid previously and ASP plus 6%. How the government pays for it is an entirely distinct issue that should be resolved separately. It does not affect the government’s legal duty to pay, nor should it delay that repayment.

More fundamentally, although Defendants previously argued that, in their “expert judgment,” “a retroactive upward adjustment [to remedy prior 340B underpayments] would require an offsetting recoupment to satisfy the statutory budget neutrality requirement,” ECF 36 at 12, in fact, nothing in federal law requires—or even authorizes—CMS to retrospectively recoup funds to achieve budget neutrality. No matter how “expert” Defendants are in the inner workings of the OPSS, their *legal* argument regarding budget neutrality is contrary to the text of the OPSS statute and contravenes their own past practice.

*First*, the text of the OPSS statute makes clear that budget neutrality applies prospectively—not retrospectively. Each year, the statute directs CMS to adjust the groups, relative payment weights, and wage indices in the OPSS *for the upcoming year*, taking into account changes in services, changes in technology, new cost data, and the like. 42 U.S.C. § 1395l(t)(9)(A).

Any such changes must be budget-neutral—which means that they cannot cause any change in “the *estimated amount* of expenditures . . . for the year.” *Id.* § 1395l(t)(9)(B) (emphasis added). As Defendants recently explained, “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.” 2021 OPPS Rule, 85 Fed. Reg. at 86,054 (emphasis added). Budget-neutrality under the OPPS is an inherently prospective exercise; it avoids increases or decreases in “overall *projected* expenditures for *the next year*.” *Am. Hosp. Ass’n v. Azar*, 964 F.3d 1230, 1234 (D.C. Cir. 2020) (emphasis added).

The only provision of the OPPS statute that Defendants have cited in support of their budget-neutrality arguments is section 1395l(t)(14)(H), but that provision likewise relates to *prospective* budget neutrality and does not authorize Defendants to retroactively recoup past payments as part of a remedy. Under sub-paragraph (14)(H), Defendants must take paragraph (14) expenditures into account when annually adjusting the groups, relative payment weights, and so on under paragraph (9)—including as affected by paragraph (9)’s budget-neutrality requirement—but because these adjustments are made under paragraph (9), they apply only to *the upcoming year*. Sub-paragraph (14)(H) does not authorize Defendants to take any action in the name of budget neutrality in any context other than their annual, *prospective* adjustments under paragraph (9).

Nowhere does the OPPS statute speak of budget neutrality in connection with retrospective changes. Accordingly, Defendants have no authority to recoup past payments to achieve budget neutrality. *See Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988) (“Retroactivity is not favored in the law. Thus, congressional enactments and administrative rules will not be construed to have retroactive effect *unless their language requires this result*.” (emphasis added)); *Claridge*

*Apartments Co. v. Comm’r of Internal Revenue*, 323 U.S. 141, 164 (1944) (“Retroactivity, even where permissible, is not favored, *except upon the clearest mandate.*” (emphasis added)).<sup>5</sup>

To make matters worse, retrospective budget neutrality would disrupt Congress’s carefully crafted prospective payment system. Although CMS each year makes all sorts of estimates that affect its projected expenditures, it ultimately “has little control” over many factors that drive its *actual* expenditures, such as “how frequently hospitals will provide [each] service.” *Am. Hosp. Ass’n*, 964 F.3d at 1235. “[A]n increase in the amount of services provided will cause an increase in overall Medicare expenditures,” sometimes over CMS’s estimates. *Id.* CMS can always use this data to refine its projections for future years, but it cannot—and does not—adjust its payment rates for prior years to achieve budget neutrality retroactively simply because it ended up paying more (or less) than it expected to. The statute does not authorize CMS to retroactively adjust payment rates or seek recoupment to achieve budget neutrality—no matter what the retroactive adjustment is intended to offset. *See H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. v. Azar*, 324 F. Supp. 3d 1, 15 (D.D.C. 2018) (noting that the OPSS’s budget neutrality requirement may not apply “where HHS has elected to make the cancer-hospital adjustment . . . well after the services are rendered, not by adjusting prospectively-set rates”).

*Second*, and unsurprisingly, although Defendants frequently fix prior errors in the OPSS, Plaintiffs have been unable to identify *a single instance* in which Defendants offset the cost of

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<sup>5</sup> Elsewhere, the government has recognized that any agency authority to issue retroactive rules must be set forth in exceedingly clear statutory language. *See* Gov’t Memo., *H Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Price*, No. 1:16-cv-2337-TJK, ECF No. 16-1, at 25 (D.D.C., filed July 17, 2017) (“Generally, retroactive applications of a law are strongly disfavored, as they disrupt legitimate expectations and disturb settled transactions. An agency’s ability to implement a retroactive rule thus depends on whether Congress expressly authorizes retroactive rulemaking in statutory text. A mere statutory grant of legislative rulemaking authority is not sufficient—rather, Congress must convey the power to engage in retroactive rulemaking in very plain words. Indeed, cases where the Supreme Court has truly found retroactive effect adequately authorized by a statute have involved statutory language that was so clear that it could sustain only one interpretation.” (cleaned up and citations omitted)).

doing so by retroactively recouping prior payments to providers. Here are a few examples of Defendants fixing prior errors *without* recouping prior payments to achieve budget neutrality:

- In 2007 HHS retroactively adjusted payment rates to several rural hospitals without offsetting recoupments to achieve budget neutrality, an approach which the Court noted in *H. Lee Moffitt*, 324 F. Supp. 3d at 15; *see also* 2007 OPPS Rule, 71 Fed. Reg. 67960, 68010 (Nov. 24, 2006).
- In 2015, CMS realized that its OPPS payments in 2014 and 2015 had been too high because it had excessively increased the conversion factor when it began packaging clinical diagnostic laboratory tests into its OPPS payments rather than paying for them separately using the Clinical Laboratory Fee Schedule. Upon recognizing its error, CMS reduced the conversion factor beginning in 2016 to prevent further overpayments going forward, but it did “not recoup ‘overpayments’ made for CYs 2014 and 2015.” 2016 OPPS Rule, 80 Fed. Reg. 70,298, 70,354 (Nov. 13, 2015).
- For the Inpatient Prospective Payment System (IPPS), although annual area wage index adjustments must be budget-neutral, 42 C.F.R. § 412.64(e)(1)(ii), CMS can revise a wage index in response to an adverse judicial decision without any need for corresponding changes to achieve budget neutrality. *See id.* § 412.64(l).

Indeed, Plaintiffs are aware of only a single instance when Defendants recouped past overpayments caused by a policy change under a prospective payment system, but they did so only pursuant to *express authorization from Congress*. In that lone example, CMS changed certain documentation and coding policies under the IPPS for 2008 and recognized that those changes might lead to higher aggregate expenditures that did not reflect actual changes in services. 2008 IPPS Rule, 72 Fed. Reg. 47,130, 47186 (Aug. 22, 2007). After CMS announced the changes, Congress acted twice to give CMS narrow, specific authority to reduce payment rates in future years to offset past overpayments caused by the policy changes. *See* TMA, Abstinence Education, and QI Programs Extension Act of 2007, Pub. L. No. 110-90, § 7, 121 Stat. 984, 986–97 (2007) (authorizing CMS to reduce 2010–2012 IPPS payment rates to offset any overpayments in 2008–2009); American Taxpayer Relief Act of 2012, Pub. L. No. 112-240, § 631(b), 126 Stat. 2313 (2013) (authorizing CMS to reduce 2014–2017 IPPS payment rates to offset \$11 billion in

overpayments from 2008–2013). Congress “knows exactly how” to give CMS express authority to offset past Medicare overpayments “when it wishes,” but did not do so here. *Ysleta Del Sur Pueblo v. Texas*, 142 S.Ct. 1929, 1942 (June 15, 2022); *see generally* *Brimstone R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928) (“The power to require readjustments for the past is drastic. It . . . ought not to be extended so as to permit unreasonably harsh action *without very plain words.*” (emphasis added)).

Despite this statutory text and regulatory history, Defendants have offered no cogent legal justification, aside from their “expert judgment,” ECF 36 at 12, as to why they would be required (or allowed) to do so in this case. They have *never* identified the requisite clear language in the OPSS statute that would authorize retrospective recoupment in the name of budget neutrality, and they have *never* explained why this situation justifies such an unprecedented action. In ordering Defendants to promptly correct past underpayments of 340B claims, the Court also should hold that Defendants have no authority to offset their remedial payments through retroactive recoupments.

**C. The equities favor the Court ordering and closely supervising the remedy in this case.**

As Defendants have acknowledged, “an injunction is an equitable remedy – the scope of which should be guided by equitable principles.” ECF 36 at 9. Equitable principles dictate that the Court should promptly order the remedy itself.

Here, “basic equitable principles of fairness,” *United States v. Fuller*, 409 U.S. 488, 490 (1973), support prompt repayment of the unlawful reimbursement cuts *without* resort to a legally unsupported budget neutrality argument. There can be no question that 340B hospitals have been unlawfully deprived of critical funds. And 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. Hosp. Ass’n*, 142 S. Ct. 1896, at \*13. Yet for five years, Defendants deprived hospitals of this limited funding by stubbornly persisting with legal arguments that both this Court and a unanimous Supreme Court rejected.

During that period, these hospitals struggled to care for patients amidst a once-in-a-generation pandemic. Indeed, a recent study found that, at the onset of the COVID-19 pandemic in 2020, 340B disproportionate share (DSH) hospitals saw a 74% drop in average operating margins—which were already negative—from -3.5% in 2019 to -6.1% in 2020. *See* Steven Heath, *et al.*, *340B DSH Hospitals Increased Uncompensated Care in 2020 Despite Significant Financial Stress* at 1 (July 20, 2022), [https://www.340bhealth.org/files/Dobson\\_DaVanzo\\_Op\\_Margins\\_and\\_UC\\_FINAL.pdf](https://www.340bhealth.org/files/Dobson_DaVanzo_Op_Margins_and_UC_FINAL.pdf)). The drop in average margins resulted in part from 340B DSH hospitals’ substantial increase in average costs of uncompensated and unreimbursed care, *id.* at 3–4, precisely the types of costs that the 340B program is designed to help offset. At the onset of the pandemic, 340B DSH hospitals began to bear the overall costs of uncompensated and unreimbursed care *even more* disproportionately than before. *See id.* at 1, 4 (340B DSH hospitals accounted for 67.4% of all such costs in 2020, compared with 64.1% in 2019, despite representing just 44% of all hospitals). Speedy repayment of 340B hospitals is crucial, and fairness dictates that the government repay them promptly.

Likewise, fairness dictates that the government not penalize other hospitals—which have long spent the funds that the government may seek to recoup—for Defendants’ own mistakes. *See Freeman v. Pitts*, 503 U.S. 467, 487 (1992) (“Equitable remedies must be flexible if these underlying principles are to be enforced with fairness . . . .”); *Concord Line Co. v. Just Oil & Grain Pte Ltd.*, 2010 WL 2382414, at \*3 (S.D.N.Y. June 14, 2010) (“Sitting in equity, a court can tailor remedies in accordance with practicality and in the interest of justice.”). A wide variety of hospitals

would be unfairly impacted by any attempt to claw back past reimbursements. For example, when implementing their unlawful reimbursement cuts, Defendants exempted (1) rural sole community hospitals, (2) children’s hospitals, (3) certain cancer hospitals, and (4) critical access hospitals. 2018 OPSS Rule, 82 Fed. Reg. 59,216, 59,355, 59,366 (Dec. 14, 2017). If Defendants attempted to achieve retrospective budget neutrality, these entities would be forced to return or forego vital funding, even though they already provide important healthcare services at exceedingly low (or often negative) margins.

If, as the government argued, equitable principles apply here, then equity points in a single direction: a remedial order that Defendants promptly repay 340B hospitals without any attempt to recoup funds from other hospitals.

In any event, the Court should closely supervise Defendants during the remedial phase of this case. The government has been on notice for several years—at least since this Court’s decision—that their reimbursement cuts were potentially unlawful. During that time, they should have at least contemplated a remedy. Given how much time has already passed and the profound effects on 340B hospitals, this Court should retain jurisdiction over the case and require monthly status reports to ensure that Defendants do not delay remedying their unlawful conduct.

When the Court previously decided not to retain jurisdiction during a remand, it cited “pragmatic considerations.” Order, ECF 59 at 4. But those considerations no longer apply. Specifically, after initially deciding to retain jurisdiction to supervise remand proceedings, *see* Order, ECF 50 at 16, the Court granted Defendants’ request to reconsider that ruling, in significant part because “retention of oversight over remand to the agency ‘call[ed] into question the finality of the remand order,’” and the Court wanted “[t]o afford the parties the opportunity for expedited review by the D.C. Circuit” to enable “prompt resolution of this suit.” Order, ECF 59 at 4. Now

that the appellate process has run its course and Supreme Court has unanimously held that Defendants' policy of underpaying 340B Hospitals is unlawful, it is entirely appropriate for the Court to retain jurisdiction and order defendants to file a status report every 30 days.

**CONCLUSION**

Plaintiffs respectfully request that the Court hold unlawful Defendants' policy of underpaying 340B claims pursuant to the 2020, 2021, and 2022 OPPS Rules. Plaintiffs further request that the Court promptly order Defendants to pay 340B Hospitals the difference between what they were paid on 340B claims in 2018 through 2022 and what they would have been paid at a rate of ASP plus 6%, plus applicable interest, without seeking to recoup funds from other hospitals. Plaintiffs also urge that the Court retain jurisdiction and require a status report every 30 days.

Dated: August 3, 2022

Respectfully submitted,

*/s/ William B. Schultz*

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**CERTIFICATE OF SERVICE**

I hereby certify that, on August 3, 2022, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

*/s/ Ezra B. Marcus* \_\_\_\_\_

Ezra B. Marcus

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL  
ASSOCIATION,  
*et al.*,

*Plaintiffs,*

–v–

XAVIER BECERRA, in his official capacity as  
the Secretary of Health and Human Services, *et*  
*al.*,

*Defendants.*

Civil Action No. 18-2084 (RC)

**[PROPOSED]  
ORDER**

Having considered Plaintiffs' Motion to Hold Unlawful and Remedy Defendants' Past Underpayment of 340B Drugs, and the opposition thereto, the Motion is **GRANTED**; it is

**DECLARED** that Defendants' policy of underpaying for 340B Drugs pursuant to the 2020, 2021, and 2022 OPPS Rules is unlawful; it is

**ORDERED** that Defendants must pay 340B hospitals, for all claims that were paid a rate of ASP minus 22.5% pursuant to the 2018 through 2022 OPPS Rules, the difference between the amounts that were paid and the amounts that would have been paid on those claims at a rate of ASP plus 6%, plus applicable interest under 42 C.F.R. § 405.378 or otherwise; it is

**ORDERED** that Defendants may not offset these remedial payments through other changes designed to achieve budget neutrality; and it is

**ORDERED** that Defendants must file a status report within 30 days of this Order, and every 30 days thereafter, concerning their remedial efforts.

The Court will retain jurisdiction of this case to ensure Defendants' compliance with this Order.

Dated: \_\_\_\_\_, 2022

\_\_\_\_\_  
Hon. Rudolph Contreras  
United States District Judge