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)**

REPLY IN SUPPORT OF PLAINTIFFS' MOTION TO HOLD UNLAWFUL AND REMEDY DEFENDANTS' PAST UNDERPAYMENT OF 340B DRUGS

HHS's response brief is remarkable for what it does *not* say. Despite conceding that it has maintained an unlawful payment policy for five years, underpaying 340B hospitals by billions of dollars, HHS steadfastly refuses to recognize its obligation to promptly repay Plaintiffs and their members. And despite having now had years to devise a remedy in the event of an adverse final decision—and more than three months since the Supreme Court's ruling—HHS displays absolutely no urgency about implementing a remedy. Instead, resorting yet again to general principles of "deference," HHS Opp'n at 2, HHS argues that it should be given free rein to devise a remedy on its own timeline, with no limitations and no oversight by this Court.

This Court should reject HHS's request for indefinite delay and unfettered discretion. Significantly, HHS does not dispute that the Court can direct an agency to take discrete action when "there is 'only one rational course' for the Agency to follow upon remand." *Huff v. Vilsack*, 195 F. Supp. 3d 343, 364 (D.D.C. 2016) (Jackson, K. J.) (citation omitted); *see* HHS Opp'n at 10.

And here, HHS has only one option for what it must do to remediate its unlawful behavior: pay 340B hospitals the difference between what HHS previously paid and ASP plus 6%.

HHS resists this straightforward conclusion, arguing that it has "multiple potential ways" to correct its unlawful underpayments. HHS Opp'n at 10. But for some purported alternatives, HHS confuses *what* it must do with *how* to do it. There is a critical difference between being ordered to promptly repay hospitals the money they are owed, as Plaintiffs request, and strictly specifying how and when those hospitals should be repaid. Put another way, this Court may give HHS limited discretion to decide *how* to correct its past underpayments (*e.g.*, to pay all at once, or over a reasonable period of time), and Plaintiffs would not oppose giving HHS an opportunity to propose a timeline *in the context of this litigation*—especially now that HHS has received the comments it sought on the remedy in this case. *See* HHS Opp'n at 5 (noting end of comment period).

At the same time, however, most of HHS's purported alternatives—including conducting a new cost acquisition survey, engaging in retrospective budget neutrality clawbacks, and promulgating a retroactive rule—are manifestly unlawful and *not* legitimate courses to pursue on remand. Red herrings are not rational courses. It is therefore perfectly appropriate for this Court to decide whether HHS's purported "multiple potential" remedies are lawful and rational, for it should not allow HHS to rely on illegal alternatives as a way of obtaining further delay.

HHS's arguments regarding budget neutrality are illustrative. It is highly significant that HHS has *never* responded to Plaintiffs' argument that, under the text of the OPPS statute, budget neutrality can be used only to set future payments for Medicare items and services because it is tied to "the *estimated* amount of expenditures" for an upcoming year. 42 U.S.C. § 1395*l*(t)(9)(B) (emphasis added); *see.* Pls.' Mot., ECF 69, at 7–9; *see also* ECF 73-1 at 4–6 (amici making same

argument); ECF 33-1 at 4–6 (same). HHS's silence suggests it in fact has no textual authority, which may explain why HHS has been unable to identify a single prior instance in which it recouped past OPPS payments in the name of budget neutrality. Faced with the pure legal question whether retrospective budget neutrality is a permissible course for HHS to follow, the Court should decide whether HHS is authorized to make budget neutrality adjustments retrospectively under the OPPS statute. In any event, as discussed below, the question of whether Plaintiffs are entitled to payment of ASP plus 6% and the question of budget neutrality are separate, and the Court can rule that Plaintiffs are entitled to prompt repayment regardless of the timing or substance of any budget neutrality decision.

It is in no one's interest to send the parties off on years of potential disputes about legal issues that should be resolved now under the governing "one-rational-course" legal standard. *See Donovan ex rel. Anderson v. Stafford Constr. Co.*, 732 F.2d 954, 961 (D.C. Cir. 1984) ("Since all the evidence bearing upon the issue is contained in the record before us, however, we believe that a remand on this issue would serve no purpose. This is particularly so in light of our ultimate holding that only one conclusion would be supportable."). As then-Judge Jackson correctly put it: "[N]o regulated party should be trapped in a hamster wheel of perpetual administrative process." *Huff*, 195 F. Supp. 3d at 364.

Finally, it is crucial that the Court retain jurisdiction to supervise HHS's remedial efforts, which even HHS acknowledges is within the Court's discretion. HHS Opp'n at 21. Given that HHS has displayed no sense of urgency to fix statutory violations that carry consequences that are unprecedented in the history of the OPPS statute, there is no reason to expect that HHS will act within a reasonable time without Court supervision. Such delay is particularly problematic given the "deteriorating" financial condition of non-profit hospitals and health systems, *see* FitchRatings,

2022 Mid-Year Outlook: U.S. Not-for-Profit Hospitals and Health Systems (Aug. 16, 2022), and the fact that margins for all U.S. hospitals are "down 37% relative to pre-pandemic levels and "more than half of hospitals are projected to have negative margins through 2022." KaufmanHall, *The Current State of Hospital Finances: Fall 2022 Update*, Am Hosp. Ass'n (Sept. 15, 2022). Defendants should not be allowed to deny already-suffering hospitals the vital funding to which they are legally entitled. This Court should retain jurisdiction to provide sufficient oversight to ensure HHS promptly effectuates an appropriate remedy.

ARGUMENT

I. Defendants Concede That They Unlawfully Underpaid for 340B Drugs Pursuant to the 2018, 2019, 2020, 2021, and 2022 OPPS Rules.

HHS "agree[s] with Plaintiffs," as it must, that "the 2020, 2021, and 2022 OPPS Rules are unlawful" in light of the Supreme Court's ruling that the 2018 and 2019 Rules were unlawful. HHS Opp'n at 6. All parties now agree that the Court should hold those rules unlawful insofar as they vary the reimbursement rate for 340B hospitals from ASP plus 6%.

It is worth pausing on the magnitude of what is now undisputed. For five years, HHS implemented an unlawful policy of underpaying 340B hospitals. As a result of this policy, hospitals that serve America's most vulnerable patients were deprived of billions of dollars to which they were legally entitled under the OPPS statute. HHS adhered to its policy in the face of repeated public comments, persistent litigation, and a decision from this Court identifying the policy's illegality. To make matters worse, after the Supreme Court granted *certiorari* in June 2021, HHS apparently failed to engage in any responsible contingency planning for the possibility that the policy may be held unlawful. *See* Pls.' Mot. to Vacate the Unlawful Portion of the 2022 OPPS Rule, ECF No. 67 at 6. This course of conduct is remarkable, and it has had enormous

adverse effects on hospitals and the patients they serve. As far as Plaintiffs are aware, there is no parallel in the near-20-year history of the OPPS statute. At this point, it seems that only an order from this Court can force the agency to promptly cease and remedy its illegal conduct.

II. The Only Rational Course Is for Defendants to Promptly Correct Their Underpayments for 340B Drugs Under the 2018 to 2022 OPPS Rules.

It is "well established" that, "when there is only one rational course for the agency to follow upon remand," a court may order an agency to perform a "discrete agency action" that the agency "is required to take." *Huff*, 195 F. Supp. 3d at 362, 364 (Jackson, K. J.); *see, e.g.*, *Donovan ex rel. Anderson v. Stafford Constr. Co.*, 732 F.2d 954, 961 (D.C. Cir. 1984) (reversing agency decision based on a legal error and declining to remand to allow the agency to consider an issue it had not yet reached because, based on court's review of the record, "only one conclusion would be supportable" on remand). Directing agency action on remand is especially appropriate when a dispute has been ongoing for a long period of time, and it would be inequitable to subject a party to further administrative procedures whose outcome should be a certainty. *E.g.*, *Huff*, 195 F. Supp. 3d at 362–64 (ordering agency to grant application on remand that it had unlawfully denied because that was the "one rational course for the Agency to follow on remand," and because "[t]his saga has gone on long enough").

Here, there is only one rational course for the agency to follow. Much as HHS tries to overcomplicate matters by discussing remedial options that are unlawful or irrational, the remedy that HHS must implement in this case is straightforward. Based on the Supreme Court's reasoning, HHS' 2018 to 2022 policies were unlawful insofar as they resulted in HHS paying 340B hospitals less than ASP plus 6%—the amount HHS was paying all of the non-340B hospitals. To fix the

violation, HHS must promptly pay 340B hospitals the difference between ASP plus 6% and what they were previously paid. That is the end of the analysis.

HHS' asserted options for correcting its five years of underpayments do not demonstrate that it has more than one rational course. By presenting this Court with several manifestly illegal alternatives in support of a plea for complete deference, HHS itself has put these issues squarely on the table for the Court to evaluate in the context of *this* litigation—not in any subsequent litigation following a remand. Because the relevant legal standard requires judicial action when there is "only one *rational* course," this Court should determine whether Defendants' so-called "options" are *irrational*. *See, e.g.*, *Fogg v. Ashcroft*, 254 F.3d 103, 111–12 (D.C. Cir. 2001) (determining that "[o]nly one conclusion would be supportable" on remand because court's interpretation of agency regulation excluded other possibilities); *Donovan*, 732 F.2d at 961 (concluding that "only one conclusion would be supportable" on remand because court's review of factual record excluded other possibilities). They are.

First, HHS argues that it should have the option of repaying 340B hospitals what they are owed through a periodic increase in future payments. *See* HHS Opp'n at 10–12. HHS contends that "the authority supporting an agency's discretion to implement a prospective remedy has only gotten stronger" in light of *Shands Jacksonville Medical Center, Inc. v. Azar*, 959 F.3d 1113 (D.C. Cir. 2020), where the D.C. Circuit affirmed HHS's decision to remedy a past violation through a prospective payment increase. HHS Opp'n at 11. But this remedial mechanism is entirely consistent with Plaintiffs' request for an order requiring "prompt" repayment. In arguing otherwise and relying on *Shands*, HHS mistakes *what* it must do with *how* to do it.

Contrary to HHS's assertions, Plaintiffs do not dispute that HHS can be given some latitude to determine *how* to repay 340B hospitals. But that does not necessitate a new, protracted process,

whether by rulemaking or otherwise. Defendants have had five years and two comment periods to consider this question, and they can easily propose alternatives for *how* to repay 340B hospitals in the context of this litigation. "This saga has gone on long enough." *Huff*, 195 F. at 362–64 (Jackson, K. J.); *see Tallahassee Memorial Regional Medical Center v. Bowen*, 815 F.2d 1435, 1456 (11th Cir. 1987) ("The litigation has already lasted at least five years. If the 1986 rule were given retroactive effect for these appellee hospitals, the hospitals have indicated that they would go through the pointless administrative review process just to return to court to challenge the 1986 rule. The new litigation would likely run three or more years beyond that point."). The Court can and should use its remedial discretion in this litigation to establish a prompt timeline for HHS to repay 340B hospitals the money they are owed.

Second, HHS should not be permitted to resist an order requiring payment of ASP plus 6% by invoking the possibility of conducting a survey of hospitals' acquisition costs. Conducting a survey in 2023 to fix unlawful payments from 2018 to 2022 is not a "rational course" for HHS to follow, and HHS offers no support for its assertion that it could lawfully do so.

Any attempted retrospective application of a survey to the 2018-2022 calendar years would also violate both the OPPS statute and basic retroactivity principles. A review of the OPPS statute demonstrates that the survey mechanism under the OPPS statute is designed to work *prospectively*. *See* 42 U.S.C. § 1395*l*(t)(14)(D). For starters, the survey mechanism is located within the "prospective payment system," as part of a statute that was designed to set rates in a forward-looking manner. *See* 42 U.S.C. § 1395*l*(t)(1)(A); *Georgetown Univ. Hosp. v. Bowen*, 821 F.2d 750, 758 (D.C. Cir. 1987) ("The Secretary invokes the broader purposes of the statute to justify his regulations: he argues that 'the core of a prospective system—its forward-looking point of view—demands that the rate be capable of certain determination prior to the provision of services.' . . .

To this extent, then, the new Medicare scheme reflects 'traditional' rate-setting principles relied on by the Secretary: fixed rates set upfront encourage industry to trim its costs to stay within these rates, while retrospective adjustments undermine such incentives."). More specifically, the statute directs GAO to conduct surveys in 2004 and 2005, and for HHS to use the resulting survey data when setting rates "for 2006." 42 U.S.C. § 1395l(t)(14)(D)(i)(I). Congress further directed HHS to "conduct periodic surveys to determine the hospital acquisition cost *for use in setting the payment rates*." *Id.* at 1395l(t)(14)(D)(ii) (emphasis added). HHS has *already* set the payment rates for 2018 through 2022 *without* the statutory survey data, using the statutory methodology that does not require such data.

If, in the context of a *prospective* payment system, Congress had intended to allow HHS to set a payment rate in a regulation and then later conduct a survey and retroactively change what it owes providers on the basis of the later survey, it would have said so. To read the statute any other way would undermine the prospective design of the OPPS system and impermissibly invite HHS "to violate the rulemaking requirements of the APA with impunity," *Georgetown Univ. Hosp.*, 821 F.2d at 758, *quoted in Bowen v. Georgetown University Hospital*, 488 U.S. 204, 216–25 (1988) (Scalia, J., concurring); *see Bergerco Canada v. U.S. Treasury Department*, 129 F.3d 189, 192–93 (D.C. Cir. 1997) (treating Justice Scalia's concurring opinion in *Bowen* as substantially authoritative). Having declined again and again, year after year, to conduct or rely on a cost acquisition survey, HHS may not now conduct a new one and apply it retroactively to resuscitate a result that the Supreme Court unanimously invalidated.

It also is impossible to take HHS's suggestion of a new cost acquisition survey seriously as a practical matter. HHS has not taken any action toward such a survey despite having had ample time to react to the Supreme Court's decision. In fact, in its current rulemaking, HHS has not even

proposed conducting a new survey with which to set rates for the 2023 calendar year, let alone for past years. *See* 2023 OPPS Proposed Rule, 87 Fed. Reg. 44,502, 44,649 (July 26, 2022) ("But again, in light of the Supreme Court's decision, we fully anticipate adopting, in the final rule, a policy of paying ASP+6 percent for 340B-acquired drugs and biologicals."). A new survey would require reevaluating payment rates for *all* hospitals—not just 340B hospitals—and would require statistically significant data for each drug in all five years. *See* 42 U.S.C. § 1395*l*(t)(14)(D)(iii) (survey must "generate a statistically significant estimate" of average costs "for each specified covered outpatient drug"). As Plaintiffs have explained, the last time HHS conducted a survey, the process took *over a year*, and the resulting survey did not meet the requirements of the statute. *See* Reply in Supp. of Pls.' Mot. to Vacate the Unlawful Portion of the 2022 OPPS Rule, ECF 75, at 4–5. And that was to set rates for only a *single year*.

HHS does not acknowledge these realities. Even if a retroactive survey were lawful, it would be wholly irrational for HHS to delay implementing a remedy by starting at the very beginning of a process that could take many years more. The only rational course is for HHS to promptly give 340B hospitals the benefit of the rate that HHS paid to everyone else.

HHS further attempts to overcomplicate the remedial question in this case by framing an order requiring payment of ASP plus 6% as the sort of "permanent injunction" that would need to satisfy "the legal standard governing issuance of an injunction." HHS Opp'n at 7 (citing *Ramirez v. U.S. Immigrations & Customs Enf't*, 568 F. Supp. 3d 10, 28 (D.D.C. 2021)). But HHS has *already* set a payment rate of ASP plus 6% for separately payable drugs for each year at issue in this case, and its specific policy of paying less to 340B hospitals is unlawful insofar as it varies the rate for those hospitals from the generally applicable rate. Ordering HHS to make up the difference between what 340B hospitals were previously paid and ASP plus 6% is simply the equivalent of

setting aside the unlawful exception for 340B hospitals, which is "[t]he ordinary practice" after agency action is held unlawful. *United Steel v. Mine Safety & Health Admin.*, 925 F.3d 1279, 1287 (D.C. Cir. 2019); *see also Ogala Sioux Tribe v. U.S. Nuclear Regulatory Comm'n*, 896 F.3d 520, 535 (D.C. Cir. 2018) (explaining that "the standard courts must apply in granting injunctive relief . . . is not the standard for the less drastic APA remedy of vacatur"). To be sure, vacatur sometimes is not appropriate when an agency rule merely has "procedural deficiencies" and the agency "may be able to rehabilitate its rule on remand." *Shands*, 949 F.3d at 1118. But here, the Supreme Court has made clear that HHS's payment policy is categorically unlawful insofar as it resulted in 340B hospitals being paid less than ASP plus 6%. *See generally Long Island Power Auth. v. FERC*, 27 F.4th 705, 717 (D.C. Cir. 2022) ("Because the controlling tariff provision is unambiguous, FERC cannot rehabilitate its preferred interpretation on remand."). Setting aside HHS's differential treatment of 340B hospitals and ordering Defendants to eliminate the underpayment, which is equivalent to vacatur, is the appropriate remedy.[1]

III. Retrospective Recoupment Is Not a Rational Course Because HHS Has No Authority to Offset its Remedial Payments Through a Backward-Looking Budget Neutrality Adjustment.

HHS again raises the possibility of retrospective budget neutrality as a reason for remanding the case to the agency in the first instance. This argument fails for two reasons, both of

[1] HHS also takes issue with Plaintiffs seeking relief that would apply to "340B hospitals" generally, rather than only to Plaintiffs and their members. HHS Opp'n at 9–10. Even if HHS is technically correct that a remedy ordered by this Court cannot extend beyond Plaintiffs and their members, those entities comprise 80% of 340B hospitals nationwide. Those hospitals, at the very least, deserve prompt repayment. More fundamentally, the challenged policy applies to 340B hospitals generally. In seeking a remedy with respect to all 340B hospitals, Plaintiffs are simply acknowledging the reality that HHS has no lawful basis to enact one remedy for member-hospitals that are involved in this lawsuit and another remedy for hospitals that are not.

which are even stronger now than they were three-and-a-half years ago when this Court initially considered them.

First, as Plaintiffs previously explained, Defendants' invocation of budget neutrality mistakes *whether* the government should be ordered to fix its unlawful underpayments with *how* it should do so. The question of whether HHS makes a budget neutrality adjustment to offset the effects of the remedy is distinct from the remedy itself, and it need not be resolved for the Court to order HHS to promptly repay 340B hospitals the money that they are owed. *See* Pls.' Mot. at 7. While it may be true that "HHS's reduction of the 340B hospital reimbursement rates and the corresponding increases to other OPPS payments were inextricably linked" in the past when the agency was operating under the annual prospective payment system, HHS Opp'n at 15, HHS offers no explanation why these issues are inextricably linked *now*, especially after the Supreme Court has rejected HHS's 340B payment policy. Following that decision, only a single remedy is possible: Defendants must repay 340B hospitals the difference between what they were paid previously and ASP plus 6%. How the government makes up this difference—including whether it attempts to apply retrospective budget neutrality under the OPPS statute, a *post hoc* rulemaking under the general retroactivity provision, *see* HHS Opp'n at 16 n.3, or some other authority it seeks to test out—is an entirely separate issue that need not impede an order requiring prompt repayment.[2]

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[2] HHS cites *Citrus HMA, LLC v. Becerra*, 2022 WL 1062990 (D.D.C. Apr. 8, 2022), to suggest that budget neutrality concerns weigh against ordering any remedy. *See* HHS Opp'n at 14–15, 20–21. But in *Citrus HMA*, HHS argued that budget neutrality concerns weighed against any court intervention *at all*—a position that the Supreme Court has now rejected. *See Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1903 (2022). Although the court in *Citrus HMA* did reference budget-neutrality considerations in ultimately deciding to remand without vacatur, the court did not consider an argument, like the one Plaintiffs present here, that a retrospective budget neutrality

Second, and more fundamentally, retrospective budget neutrality is unlawful and thus is not a rational course for the agency to follow. Despite having had many years to consider this legal question, HHS does not offer *any* textual interpretation of the OPPS statute in support of its authority to make retrospective budget neutrality adjustments. As Plaintiffs explained in their opening brief (at 7-9), budget neutrality is an inherently prospective exercise, which the statutory text confirms. The budget neutrality provision is set forth in a subsection entitled "Periodic review and adjustments components of *prospective* payment system," 42 U.S.C. § 1395*l*(t)(9) (emphasis added), and budget neutrality is expressly tied to "the *estimated* amount of expenditures" in an upcoming year. 42 U.S.C. § 1395*l*(t)(9)(B) (emphasis added). The plain text of the OPPS statute says nothing about past years or retrospective clawbacks; it only addresses future estimates and forward-looking periodic reviews. HHS offers no response to this text.

Instead, Defendants' answer to Plaintiffs' textual arguments is to cite language from *Amgen, Inc. v. Smith*, 357 F.3d 103 (2004). *See* HHS Opp'n at 15–16. But *Amgen* itself contains no textual analysis of the relevant budget neutrality provision. In fact, *Amgen* is addressed to a different section of the OPPS statute; its discussion of budget neutrality merely asserted HHS's recoupment authority without any mention of 42 U.S.C. § 1395*l*(t)(9); and its conclusory discussion of budget neutrality was not essential to the D.C. Circuit's holding. As this Court has

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adjustment would be foreclosed under the statutory text. *See* 2022 WL 1062990, at *10. Moreover, any such an argument in *Citrus HMA* would have required interpretation of a different budget-neutrality provision. And unlike the provision at issue in this case, which is inherently prospective because it requires budget-neutralizing "*estimated* payments," 42 U.S.C. § 1395*l*(9)(B) (emphasis added), the provision in *Citrus HMA* arguably applies retrospectively because it requires budget-neutralizing "the aggregate payments *made* . . . in a fiscal year." 42 U.S.C. § 1395ww, Note, Balanced Budget Act of 1997, Pub. L. 105-33, § 4410(b) (1997) (emphasis added).

already explained, *Amgen* "does not appear to have definitively weighed in" on whether budget neutrality applies to remedial payments. Order, ECF 50 at 20. *Amgen* thus cannot provide the legal authority for Defendants to claw back billions of dollars from hospitals that have long spent that money—including during a once-in-a-century pandemic.

If all of this were not enough, the Supreme Court's decision in this case casts doubt on the continued viability of *Amgen*'s unexplained suggestion that budget neutrality applies to remedial payments. HHS's current argument based on *Amgen* is reminiscent of the argument that HHS previously made in this case with respect to statutory preclusion, which the Supreme Court unanimously rejected. Before the Supreme Court, HHS "argue[d] that allowing judicial review of the 2018 and 2019 reimbursement rates would be impractical because the agency is required to operate the program on a budget-neutral basis." *Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1903 (2022). Rejecting that argument (in which HHS expressly relied on the language in *Amgen* that it now continues to invoke here[3]), the Supreme Court held that any concerns about the impact of budget neutrality had no bearing on whether the statute permitted judicial review because they could not "override" statutory text. *Id.*

Not only does *American Hospital Association* undercut the passage from *Amgen* on which HHS has relied throughout this litigation, but it offers a vital reminder about the importance of statutory text. As Plaintiffs observed in their opening brief (at 11), "[t]he 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*." *Brimstone R. & Canal Co. v. United States*, 276 U.S. 104, 122 (1928). Here, Defendants offer *no words*—let alone "very plain" ones. Allowing HHS to claw

[3] *See* Resp't's Br., *Am. Hosp. Ass'n v. Becerra*, No. 20-1114, at 22 (S. Ct., filed Oct. 20, 2021).

back billions of dollars from cash-strapped hospitals on this basis would be contrary to the OPPS statute—and thus not a rational course for the agency to follow.

Defendants' inability to muster a statutory argument for retrospective budget neutrality should be the end of the matter. But it is striking that HHS also cannot cite a single historical example in which it made a budget neutrality adjustment to offset the effects of a court-ordered remedy, or in which it recouped prior payments to achieve budget neutrality absent express congressional authorization. Notably, Plaintiffs highlighted the lack of any such precedent in their Motion (at 9-10).[4] HHS's failure to respond with a single instance in which it applied budget neutrality retrospectively confirms that it has never done so, and it is a further indication that HHS has no statutory authority to do so now, notwithstanding its briefs in this litigation.

Finally, because HHS has no argument for how to square retrospective budget neutrality with the text of the OPPS statute, it invokes a *different* statute—the general Medicare retroactive rulemaking statute, 42 U.S.C. § 1395hh(e)(1)(A)—which provides "limited authority" for HHS to apply certain types of changes retroactively. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1812 (2019). But while this general retroactivity statute may sometimes allow HHS to address services

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[4] Plaintiffs also noted that they "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*." Pls.' Mot. at 10. This demonstrates that Congress "knows exactly how" to give CMS express authority to offset past Medicare overpayments "when it wishes." *Ysleta Del Sur Pueblo v. Texas*, 142 S.Ct. 1929, 1942 (June 15, 2022). HHS does not address this example or argument *at all*. Instead, HHS suggests that "Plaintiffs are of course free to ask Congress to direct the agency to pay out billions of dollars without regard to budget neutrality." HHS Opp'n at 2. But this inverts law and logic. It is Defendants—not Plaintiffs—that would need new, plain statutory authority if they wanted to make a retrospective budget neutrality adjustment to offset the remedy in this case. As it did in the example Plaintiffs discussed, HHS can ask Congress for such authority if it wants it. But in the meantime, it must adhere to the current OPPS statute, which does not authorize retrospective budget neutrality adjustments.

provided in the past, HHS cannot rely on it to achieve retrospective budget neutrality when the OPPS statute—the statute that specifically addresses budget neutrality—makes budget neutrality inherently prospective. As such, HHS cannot bootstrap 42 U.S.C. § 1395*l*(t)(14)(H) or § 1395*l*(t)(9) onto the general retroactivity provision, as it suggests it can do, *see* HHS Opp'n at 16, because those provisions *foreclose* retrospective budget neutrality. HHS cannot escape its utter lack of textual support under the OPPS statute by relying on the general retroactivity provision, because its entire argument with regard to that statute ultimately depends on using the OPPS statute, 42 U.S.C. § 1395*l*(t)(9), to achieve retrospective recoupment.

Furthermore, budget neutrality is an extremely complex process, and as HHS has previously acknowledged, redoing it retrospectively would involve "huge logistical hurdles," not to mention extreme unfairness to other providers, which raises a serious question as to whether retrospective budget neutrality in the context of this case could ever be practicably accomplished, even if it were permissible. ECF 31 at 8. If Congress wanted to authorize HHS to completely invert an inherently prospective budget-neutrality process by conducting it retrospectively, with such destabilizing consequences, it would have said so explicitly in the budget-neutrality statute itself, but it did not.

Even if HHS could somehow invoke this statute, it could never satisfy the statute's terms. As HHS notes (at 16 n.3), 42 U.S.C. § 1395hh(e)(1)(A) requires the Secretary to prove that "retroactive application is necessary to comply with statutory requirements," or that "failure to apply the change retroactively would be contrary to the public interest." But HHS has backed off of any suggestion that retrospective recoupments would be statutorily *required*, *see* ECF 36 at 9–12; at most, it now suggests that it has *discretion* on the matter, *see* HHS Opp'n at 17. And HHS nowhere justifies the proposition that recouping tens of millions of dollars from individual

hospitals that already relied on that money, including during the COVID-19 pandemic, could serve the public interest. As even HHS has acknowledged elsewhere with respect to the IPPS, which is analogous to the OPPS:

> It is unclear whether the Secretary could practicably [recoup funds from other hospitals to achieve budget neutrality] given the expectations of hospitals that have relied on their already received . . . payments in making future financial decisions, particularly in light of the fact that Congress intended the IPPS to be prospective in nature.

Gov't Mem. in Supp. of Cross-Mot. for Summ. J., ECF No. 26-1 at 28, *Citrus HMA, LLC v. Azar*, No. 20-cv-707 (D.D.C., filed Feb. 1, 2021). In part for this reason, HHS previously recognized in this case that recouping prior payments to other hospitals through a retroactive rulemaking under § 1395hh(e) was not "tenable." ECF 31 at 9. In this way, yet again, HHS fails to demonstrate that recoupment is a rational choice for the agency to make.

When this Court first considered the appropriate remedy in this case more than three years ago, it concluded that there was sufficient "uncertainty surrounding" the budget neutrality issues to warrant a remand without vacatur. Order, ECF 50, at 20. The passage of time and the Supreme Court's unanimous ruling have eliminated any uncertainty. In the intervening years, HHS *still* has not identified any authority under the OPPS statute for imposing retrospective budget neutrality. HHS *still* cannot identify any historical precedent for a clawback. And the only case law on which HHS relies has been undercut by the Supreme Court's decision in this case. All of this conclusively demonstrates that HHS should not be able to resist Plaintiffs' requested relief merely by incanting the words "budget neutrality." Deciding whether retrospective budget neutrality is a lawful, rational choice for the agency to follow is a pure question of statutory interpretation. As such, "all the evidence bearing upon the issue is contained in the record before" this Court. *Donovan ex rel.*

Anderson., 732 F.2d at 961. "A remand on this issue would serve no purpose," *id*., and delay would only further harm hospitals, their patients, and the communities they serve.[5]

IV. The Court Should Retain Jurisdiction.

At a minimum, Plaintiffs urge the Court to retain jurisdiction to ensure that HHS provides appropriate relief within a reasonable period of time. Even HHS recognizes that "the Court has discretion to retain jurisdiction over a case pending completion of a remand." HHS Opp'n at 21 (citation omitted). In light of the trajectory of this litigation to date, the real possibility that HHS's actions on remand could generate years of additional administrative procedure and follow-on litigation, and HHS's lack of a demonstrated commitment to remediate its own mistakes in a prompt manner, it is crucial that the Court retain jurisdiction.

Courts can retain jurisdiction to oversee remand proceedings when there would otherwise be a "likelihood of extreme agency delay." *Baptist Med. Ctr. v. Burwell*, 2019 WL 978957, at *9 (D.D.C. Feb. 28, 2019). That is the case here. HHS has stuck to its unlawful underpayment policy through five annual rulemakings and despite years of litigation suggesting at least a possibility (and at times a likelihood) that its policy would be held unlawful. But it is not simply the considerable amount of time that has passed that makes retention of jurisdiction appropriate. This

[5] HHS argues that any Court ruling on budget neutrality would be premature on the theory that "there is presently no final agency action regarding budget neutrality for the Court to review," HHS Opp'n at 18, or alternatively that Plaintiffs "lack standing to challenge a mere potential agency action." *Id.* But Plaintiffs *are* challenging final agency action in this case through the appropriate vehicle established by the Medicare Act. For the Court to rule on HHS's authority to make an offsetting budget neutrality adjustment would be within the Court's remedial discretion within the context of addressing the unlawful action that HHS has already taken. It is especially appropriate for the Court to weigh in on a discrete legal issue like budget neutrality given that this litigation has now been ongoing for years, HHS has given no sense that it will promptly make Plaintiffs whole on its own, and a lack of guidance from this Court could set the parties off on years of delay in resolving the crucial remedy issue in this case.

Court should retain jurisdiction because HHS appears to be no closer to identifying a remedy today than it was three-plus years ago when this Court first remanded the case. Even in the months since the Supreme Court's decision, HHS has failed to issue any specific remedial proposal or otherwise take serious steps toward a remedy suggesting that it will do so on a reasonable time frame. What is more, Defendants continue to toss out possible remedies in their briefs, regardless of whether those remedies have a sound basis in law or reality. For all of these reasons, there is a very real "likelihood of extreme agency delay" in this case. Such delay would compound the years of harm that HHS's unlawful policy has already had on hospitals that are in no position to withstand billions of dollars in illegal shortfalls. *See, e.g.*, FitchRatings, *supra* at 3 (noting that "macro headwinds" for non-profit hospitals "have been more pronounced than expected" in 2022). And despite its inaction to date, HHS should be interested in prompt repayment as well. Now that there have been "final determinations" that Plaintiffs were underpaid in each of the relevant years in this case, interest on the underpayments will continue to accrue until they are remedied. *See* 42 U.S.C. § 1395*l*(j); 42 C.F.R. § 405.378(b).

Ultimately, HHS has had every opportunity to demonstrate a serious commitment to fixing its own mistakes within a reasonable period of time in the event of an adverse final decision, and it has failed to so at every turn. To help avoid further harmful delay, Plaintiffs respectfully ask the Court to retain jurisdiction, as HHS recognizes the Court has discretion to do.

CONCLUSION

HHS's payment policy for 340B hospitals from 2018 through 2022 was unlawful insofar as it resulted in those hospitals being paid less than ASP plus 6% for separately payable drugs. Plaintiffs ask the Court to order HHS to promptly remedy its unlawful policy by making up the

difference between what they were paid and ASP plus 6%, plus applicable interest. Plaintiffs urge the Court to retain jurisdiction to ensure that HHS implements a remedy within a reasonable time.

Dated: September 21, 2022

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on September 21, 2022, I caused the foregoing to be electronically served on counsel of record via the Court's CM/ECF system.

/s/ Ezra B. Marcus
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