

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

American Hospital Association, *et al.*,

Plaintiffs,

–v–

Xavier Becerra, Secretary of Health and Human
Services, *et al.*,

Defendants.

Case No. 1:18-cv-2084 (RC)

**OPPOSITION TO PLAINTIFFS’ MOTION TO HOLD UNLAWFUL AND REMEDY
DEFENDANTS’ PAST UNDERPAYMENT OF 340B DRUGS**

INTRODUCTION

Defendants agree with Plaintiffs that the Supreme Court’s decision in this case for the 2018 and 2019 calendar years effectively resolves Plaintiffs’ claims relating to the 2020, 2021, and 2022 calendar years. Because it “is ordinarily ‘the prerogative of the agency to decide in the first instance how best to provide relief,’” *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1118 (D.C. Cir. 2020), the appropriate next step in this case is a remand to the agency—without vacatur—as the Court previously concluded in rejecting arguments similar to those that Plaintiffs repeat here.

Plaintiffs nevertheless urge the Court to issue injunctive relief requiring the government to “promptly . . . [pay Plaintiffs] the difference between what they were paid and [average sales price] plus 6%.” Mot. to Hold Unlawful and Remedy Defs.’ Past Underpayment of 340B Drugs (“Mot.”), ECF No. 69 at 1-2. The Court should deny that request. Plaintiffs have not demonstrated that injunctive relief is appropriate here, nor could they given that, as the Court has already observed,

the agency has multiple potential options to remedy the disputed claims at issue. Under longstanding precedent, the choice of which remedy to implement is for the agency to consider in the first instance. If Plaintiffs are later dissatisfied by the agency's chosen remedy, they could challenge the remedy at that time, but they cannot foreclose the agency's discretion in advance of remand. Similarly, Plaintiffs' arguments regarding budget neutrality improperly seek to preemptively adjudicate issues that the agency should be permitted to consider on remand. Given that the agency has not yet determined what remedy it will implement, the question of how budget neutrality principles may impact its chosen remedy is entirely premature.

Remand without vacatur is the better option. It would afford the agency an opportunity to craft a remedy in the first instance, which is consistent with the “‘heightened deference’ that courts are to accord ‘the Secretary’s interpretation of a ‘complex and highly technical regulatory program’ such as Medicare.” *Shands Jacksonville*, 959 F.3d at 1118. Indeed, the agency has already published a notice of proposed rulemaking that seeks, among other things, “public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022[.]” 87 Fed. Reg. 44505, 44649. The Court should allow the agency to complete that administrative process and devise an appropriate solution, given the potential for disruption in the immense and complex system that has been entrusted to the agency to administer. Plaintiffs are of course free to ask Congress to direct the agency to pay out billions of dollars without regard to budget neutrality. But absent such specific legislation, the remedy issues should be addressed by the agency in the first instance.

BACKGROUND

Plaintiffs' initial complaint in this case challenged the agency's 2018 OPPS Rule, alleging that the Secretary's reimbursement rate reduction for 340B drugs violated the Administrative

Procedure Act and the Social Security Act. *See generally* Compl., ECF No. 1. On December 27, 2018, the Court entered judgment in favor of Plaintiffs, but it declined Plaintiffs’ request to vacate the 2018 Rule and to require the agency to apply the average sales price (“ASP”) plus six percent reimbursement methodology to 340B drug payments “made for the remainder of 2018[.]” Mem. Op., ECF No. 25, at 33-34. Because the rates in the 2018 Rule reflected a careful balance necessary to comply with the statutory “budget neutrality requirement”—an “important component of the Medicare Part B scheme”—the Court determined that “vacatur and the other relief sought by Plaintiffs [we]re likely to be highly disruptive.” *Id.* at 34. To avoid “havoc on the already complex administration of Medicare Part B’s outpatient prospective payment system,” the Court ordered supplemental briefing on the remedy issue. *Id.* at 35-36.

In their supplemental brief, Plaintiffs asked the Court to “order HHS to recalculate the payments due to 340B hospitals for 2018 claims” based on the statutory rate of ASP plus six percent. Pls.’ Suppl. Br. on Remedies, ECF No. 32 at 2. Soon thereafter, Plaintiffs filed a supplemental complaint challenging the 2019 OPPS Rule (the rule that was in effect at that time), *see* Suppl. Compl., ECF No. 39, and moved to permanently enjoin that rule, *see* Pls.’ Mot. for Permanent Inj. Covering 2019 OPPS Rule, ECF No. 35. That motion also sought prospective relief for the remainder of 2019. Specifically, Plaintiffs asked the Court to “order Defendants to issue an interim final rule within 30 days of the Court’s order . . . providing that 340B drugs will be reimbursed using the methodology based on the statutory default rate of ASP plus 6%[.]” *Id.* at 3. As to “340B drugs where claims were paid before the effective date of the interim final rule,” Plaintiffs requested that “the Court implement the same retrospective remedy that plaintiffs have proposed for 2018.” *Id.* at 4.

The Court denied Plaintiffs' requests for retrospective and prospective relief. Instead, it concluded that, "[r]emand, rather than an injunction, is the better course of action here." Mem. Op., ECF No. 50 at 14. As the Court observed, the "path forward is not sufficiently clear cut that this Court should chart it in the first instance." *Id.* at 15 n.15; *see also id.* at 15 & n.15 (noting the "multiple ways for HHS to remediate its underpayments" and the complicated questions relating to budget neutrality). The Court also determined not to vacate the 2018 and 2019 OPSS Rules because, among other things, "vacatur would likely be highly disruptive." *Id.* at 18. Although paying higher 340B reimbursement rates "would address Plaintiffs' harm," doing so would also raise "potentially serious administrative problems." *Id.* In particular, vacatur would complicate the issue of budget neutrality. *Id.* at 20 ("it suffices to say that the uncertainty surrounding this issue all but guarantees its resolution would be highly disruptive"). Although "[b]udget neutrality" was "likely to cause disruption regardless of whether the Court vacate[d] the 2018 and 2019 OPSS Rules," "remand without vacatur" would "allow the agency more flexibility to determine the least disruptive means of correcting its underpayments to Plaintiffs, including possibly making remedial payments in a non-budget neutral manner." *Id.* at 20 n.19.

On appeal, the D.C. Circuit ruled that the agency "reasonably interpreted" the Secretary's "adjustment authority to enable reducing [specific covered outpatient drugs] payments to 340B hospitals, so as to avoid reimbursing those hospitals at much higher levels than their actual costs to acquire the drugs." *AHA v. Azar*, 967 F.3d 818, 828 (D.C. Cir. 2020). The case proceeded to the Supreme Court, which ruled that the Medicare statute does not "afford HHS discretion to vary the reimbursement rates [for drugs] for that one group of hospitals [*i.e.*, hospitals that purchase drugs through the 340B Program] when, as here, HHS has not conducted the required survey of hospitals' acquisition costs." *AHA v. Becerra*, 142 S. Ct. 1896 (2022). On the issue of remedies,

the Supreme Court noted the government's position regarding the significance of the "budget-neutrality requirement," and the hospitals' response that there were "various potential remedies" available that would resolve budget neutrality concerns. *Id.* at 1903. But the Supreme Court explained that it "need not address potential remedies" at that stage, and it remanded the case for further proceedings. *Id.* at 1903, 1906.

On or about July 15, 2022, the Secretary published a Notice of Proposed Rulemaking ("NPRM") to revise the OPSS for 2023. *See* 87 Fed. Reg. 44505. That NPRM explains that, based on the Supreme Court's decision in this matter, the agency anticipates applying a payment rate of ASP plus six percent to 340B hospitals for 2023, and adjusting the OPSS conversion factor downward to maintain budget neutrality. *Id.* at 347-49, 352-53. The NPRM also addresses the issue of payments for 340B drugs and biologicals for years 2018 through 2022. *Id.* at 350-52. It states that the agency is "still evaluating how to apply the Supreme Court's recent decision to cost years 2018-2022" and requests "public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022[.]" *Id.* at 352. The public comment period ended on September 13, 2022. *Id.* at 2.

Upon remand of this case, Plaintiffs moved for leave to file a second supplemental complaint, which added claims challenging the OPSS rules that Defendants promulgated for 2020, 2021, and 2022. ECF No. 66. Plaintiffs also filed a motion seeking to "expeditiously . . . vacate the portion of the 2022 OPSS rule that carves out 340B drugs from the general payment rate for separately payable drugs" and "order Defendants to immediately begin reimbursing 340B drugs at ASP plus 6% for the remainder of 2022." ECF No. 67, at 2. And Plaintiffs filed another motion, at issue here, asking the Court to (1) "hold unlawful the 2020, 2021, and 2022 OPSS Rules" and

(2) “order Defendants to promptly . . . [pay Plaintiffs] the difference between what they were paid and ASP plus 6%.” Mot., ECF No. 69 at 1-2.

ARGUMENT

I. Defendants Agree that the Supreme Court’s Decision Effectively Resolves Plaintiffs’ Claims Relating to the 2020, 2021, and 2022 Calendar Years

Defendants agree with Plaintiffs that the Supreme Court’s decision in this case for the 2018 and 2019 calendar years effectively resolves Plaintiffs’ claims relating to the 2020, 2021, and 2022 calendar years. Mot. at 4. Defendants therefore do not oppose Plaintiffs’ motion to the extent it seeks a declaration that the 2020, 2021, and 2022 OPPS Rules are unlawful insofar as they vary the reimbursement rate for 340B hospitals from ASP plus six percent absent a survey of hospitals’ acquisition costs. Defendants do, however, oppose Plaintiffs’ other remedial requests.

II. Plaintiffs Are Not Entitled to Injunctive Relief

A. Once an APA Violation Has Been Found, the Court’s Inquiry Is At An End

Plaintiffs ask the Court to “order Defendants to promptly repay 340B hospitals the difference between what they were previously paid and ASP plus 6%.” Mot. at 6. Plaintiffs’ request for injunctive relief is inconsistent with decades of settled precedent, which they fail to acknowledge, much less distinguish. “[W]hen a court reviewing agency action determines that an agency made an error of law, the court’s inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards.” *County of Los Angeles v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999). It is usually inappropriate for a reviewing court to dictate precise steps the agency should take to conform its regulatory program with the court’s explanation of the law. *See id.* at 1011-12 (holding that the district court erred in retaining jurisdiction to devise a specific remedy for the agency to follow); *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (holding that the district court erred by directing the

Secretary to make new determinations based on the plaintiff's data, rather than simply remanding); *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (explaining that the district court "erred by directing the Secretary how to calculate the hospitals' [disproportionate share hospital] reimbursements, rather than just remanding after identifying the error").

As the Court of Appeals explained in *County of Los Angeles*, "[o]nce ... the district court [holds] that the Secretary had misinterpreted [the Medicare statute], it should ... remand[] to the Secretary for further proceedings consistent with its conception of the statute." 192 F.3d at 1011; *see also Shands Jacksonville*, 959 F.3d at 1118 ("Even when a court sets aside an unlawful agency action under the APA, it is ordinarily 'the prerogative of the agency to decide in the first instance how best to provide relief.'"). In other words, the function of a reviewing court ends when "an error of law is laid bare." *Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952); *see also Huff v. Vilsack*, 195 F. Supp. 3d 343, 362 (D.D.C. 2016) (explaining that remand "is generally warranted because courts prefer that agencies apply their expertise to pertinent issues of fact and law in the first instance").

Although there are some limited instances in which courts order injunctive relief in APA cases, such relief is not warranted here. Indeed, Plaintiffs' Motion largely ignores the legal standard governing issuance of an injunction. *See Ramirez v. U.S. Immigration & Customs Enf't*, 568 F. Supp. 3d 10, 28 (D.D.C. 2021) ("Success on the merits of a case 'does not automatically entitle [a plaintiff] to injunctive relief as of right.'"). A party seeking a permanent injunction must show: "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *Id.* at 21 (quoting *Monsanto*

Co. v. Geertson Seed Farms, 561 U.S. 139, 156-57 (2010)). These factors do not support injunctive relief here. In particular, Plaintiffs have not even attempted to establish irreparable harm, nor could they because it is well-settled that “in the absence of special circumstances . . . recoverable economic losses are not considered irreparable.” *Taylor v. Resol. Trust Corp.*, 56 F.3d 1497, 1507 (D.C. Cir. 1995). Here, a remand would allow the agency an opportunity to fashion a remedy to reimburse Plaintiffs’ economic losses—no further relief is necessary or appropriate at this stage. *See NRDC v. U.S. Army Corps of Eng’rs*, 457 F. Supp. 2d 198, 237 (S.D.N.Y. 2006) (denying injunctive relief in APA case and stating that the “discussion of irreparable harm, public interest, and the balance of equities is premature, however, because the plaintiffs are not without a legal remedy: remand.”).

As to the remaining equitable factors, Plaintiffs assert that 340B hospitals—like many businesses—have suffered financially in recent years because of the pandemic. Mot. at 11-12. But, again, they do not contend (much less demonstrate) that they will suffer irreparable harm in the absence of an injunction. If Plaintiffs’ point is simply that they would benefit financially from an expedited timeline for payment, that could be said in any case in which monetary relief is sought. Everyone wants to be paid sooner rather than later, but the desire for a quick payment is no reason to grant an injunction.

Also, the possibility that the agency might seek to recover payments from some hospitals does not justify denying the agency the opportunity to consider, in the first instance, whether to do so. Mot. at 12-13. The ordinary procedure is for judicial review of the agency’s remedy to occur, if at all, *after* the agency has determined that remedy on remand. *See Shands Jacksonville*, 959 F.3d at 1118. Plaintiffs cite no authority supporting the notion that a court may, in the name of

equity, preemptively conclude that a particular potential remedy that the agency might—or might not—decide to implement would be unfair to third parties, and deny a remand on that basis.

In any event, there would be nothing inequitable if the agency were to settle on a remedy that involved recovering certain payments from providers. The budget neutrality adjustment at issue here was part and parcel of the 340B payment adjustment that Plaintiffs contested. That is, absent the 340B payment adjustment, the agency would not have made the associated budget neutrality adjustment to offset the decreases in payments that would have otherwise occurred under the OPPS. The budget neutrality adjustment had the effect of increasing the payment rates for all non-drug OPPS services—including those furnished by the plaintiff hospitals themselves—which they simply ignore when they ask solely for the 340B drug claims payment amounts to be increased. The public interest clearly weighs in favor of the preservation of public funds. *See Brock v. Pierce County*, 476 U.S. 253, 262 (1986) (“[T]he protection of the public fisc is a matter that is of interest to every citizen.”). Especially considering the extraordinary amount of money at issue here, the public interest plainly favors giving the agency an opportunity to craft a remedy after consideration of all of the relevant interests.

Even if injunctive relief were appropriate here (it is not), there is no support for the inappropriately broad injunction that Plaintiffs propose. They ask the Court to order Defendants to make payments to “340B hospitals” generally. *See* Prop. Order, ECF No. 69-1. But Plaintiffs have not demonstrated that they represent all 340B hospitals. The Supreme Court has held that a “plaintiff’s remedy must be limited to the inadequacy that produced his injury in fact” and that “the Court’s constitutionally prescribed role is to vindicate the individual rights of the people appearing before it.” *Gill v. Whitford*, 138 S. Ct. 1916, 1930 (2018). It has also held that an injunction should be no broader than that necessary to provide a plaintiff relief. *Madsen v.*

Women's Health Ctr., Inc., 512 U.S. 753, 765 (1994). Plaintiffs' request for an injunction that would benefit non-plaintiffs is, therefore, overly broad and should be denied for that reason as well.

B. The Agency Has Multiple Potential Ways to Correct Its Payments for the Claims at Issue, as the Court Has Already Observed

Consistent with the above-described principles, the Court previously denied Plaintiffs' prior, similar remedial request, ruling that "[r]emand, rather than an injunction, is the better course of action here." Mem. Op., ECF No. 50 at 14. As the Court explained, "[i]njunctive relief is typically appropriate when 'there is 'only one rational course' for the [a]gency to follow upon remand" but here "there are multiple ways for HHS to remediate its underpayments[.]" *Id.* at 15 (quoting *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013)).

Plaintiffs suggest that the Supreme Court's ruling in this case somehow "changed the landscape" such that injunctive relief is now appropriate. Mot. at 4. They note the difference between the Supreme Court's reasoning and this Court's reasoning and claim that the Supreme Court's "alternative rationale effectively dictates what CMS must do to fix its violation." *Id.* at 5. According to Plaintiffs, 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%." Mot. at 4. That is demonstrably incorrect—there are multiple ways for HHS to resolve the disputed claims (as this Court has already observed), and not all those methods would pay hospitals ASP plus 6% on a drug-by-drug, claim-by-claim basis. The Supreme Court's decision—which prohibited the agency from varying payments based on hospital groups without conducting a survey—does not suggest otherwise.¹

¹ Contrary to Plaintiffs' contention that the Supreme Court's opinion effectively resolves the remedy question, the opinion indicates that there are questions relating to the remedy that still must

For example, this Court previously noted that HHS indicated it “could potentially adjust reimbursement rates in future years to make up for its underpayments in 2018 and 2019.” Mem. Op., ECF No. 50, at 15 n.15. Since the Court issued its prior remedies opinion, the authority supporting the agency’s discretion to implement a prospective remedy has only gotten stronger. Specifically, in 2020, the D.C. Circuit decided *Shands Jacksonville*, which rejected a challenge to an HHS remedy that paid hospitals prospectively to compensate for revenue lost in prior years. 959 F.3d at 1119. In that case, a group of hospitals challenged a reduction in Medicare reimbursement rates for inpatient hospital services for fiscal year 2014, and the district court remanded the rule to the agency without vacatur. *Id.* at 1115. The Secretary then increased certain Medicare rates for fiscal year 2017 to offset the past effects of the rate reduction. *Id.* On appeal, the hospitals argued that the district court erred in failing to vacate the 2014 rule or require the Secretary to provide “make whole relief” for each hospital. *Id.* But the D.C. Circuit affirmed the district court, ruling that the hospitals failed “to show that the Secretary did not make ‘a reasonable choice between the competing values of finality and accuracy’ in adopting the rate increase as an appropriate remedy for the deficient rate reduction.” *Id.* at 1119.

A prospective rate increase would be an option here—and nothing in the Supreme Court’s decision suggests otherwise. Plaintiffs’ Motion, however, seeks to foreclose that option and it expressly invites the Court to eliminate the agency’s discretion to craft an appropriate remedy. Mot. at 6 (“the Court should issue an order leaving them no discretion regarding what remedy they must accomplish”). Plaintiffs’ Motion, therefore, is inconsistent with the “‘heightened deference’

be resolved. *See AHA*, 142 S. Ct. at 1903, 1906 (discussing the parties’ positions regarding whether a remedy must be budget neutral, explaining that it “need not address potential remedies,” and remanding the case for further proceedings).

that courts are to accord ‘the Secretary’s interpretation of a ‘complex and highly technical regulatory program’ such as Medicare.’” *Shands Jacksonville*, 959 F.3d at 1118.

Another option would be for the agency to conduct a survey of hospital acquisition costs. *See AHA*, 142 S. Ct. at 1900 (citing 42 U.S.C. § 1395l(t)(14)(A)(iii)(I), (D)) (“If the agency has conducted a survey and collected that data, HHS may set reimbursement rates based on the hospitals’ ‘average acquisition cost’ for each drug.”). Such a survey could validate the rates at issue in this litigation or otherwise inform the appropriate remedy. For instance, the results of such a survey may indicate the extent to which there was an insufficient payment, if any, to remedy. Plaintiffs’ Motion, however, would foreclose the possibility of conducting a survey. As before, “Plaintiffs’ arguments for injunctive relief are unpersuasive, and the case law weighs against them.” Mem. Op., ECF No. 50, at 15.²

C. Issues Relating to Budget Neutrality Should Be Considered First By the Agency On Remand

1. The Court Should Not Preemptively Determine How Budget Neutrality Principles Might Impact the Agency’s Consideration of Remedies

The fact that there are multiple potential ways for HHS to correct its underpayments, as discussed above, is reason enough to deny Plaintiffs’ Motion. But an additional reason why the Motion should fail is that any order directing the agency to make payments to 340B hospitals

² Plaintiffs claim that Defendants “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.’” Mot. at 6 n.4. In fact, the language referenced by Plaintiffs states that “if Plaintiffs hypothetically were to prevail and obtain an order directing Defendants to reinstate the ASP+6% OPSS payment rate for 340B drugs, they could seek payment for their Medicare claims under the higher ASP+6% rate in a variety of ways[.]” *Am. Hosp. Ass’n v. Hargan*, No. 17-2447, ECF. No. 18 at 49 (D.D.C.)). The key to this passage is the first word: if. The passage does not say that plaintiffs are entitled to an order reinstating the ASP + 6% payment rate for drugs purchased through the 340B Program in 2018, but that “if” they obtained such an order (*i.e.*, the order they were seeking), they could recover their money through a variety of procedural mechanisms.

would have to resolve the related question of what, if anything, must be done to account for the budget neutrality principles that the agency followed when setting the 340B reimbursement rates. The Court should adhere to the longstanding principle that “it is ordinarily the prerogative of the agency to decide in the first instance how best to provide relief,” *Shands Jacksonville*, 959 F.3d at 1118, and allow the agency to consider budget neutrality principles in the first instance.

As the Court is aware, it previously addressed the fact that the parties have different views about the impact of budget neutrality principles here. The Court determined not to resolve the parties’ dispute over whether the agency could offset retroactive payments to account for budget neutrality, noting that the uncertainty on that issue called for the agency to consider it on remand. *See* Mem. Op., ECF No. 15, at 20 (“At this stage, it suffices to say that the uncertainty surrounding this issue all but guarantees its resolution would be highly disruptive, should the Court vacate the 2018 and 2019 OPPS Rules.”). Because there was “some question as to whether the agency’s actions must be budget neutral” the Court determined that the “path forward is not sufficiently clear cut that this Court should chart it in the first instance.” Mem. Op., ECF No. 50, at 15 n.15.

Plaintiffs and amicus curiae attempt to relitigate that issue, Mot. at 7-11; Br. of the Fed. of Am. Hosp. as Amicus Curiae in Supp. of Pls, ECF No. 74, at 4-17, but their arguments are still premature. The agency has not yet made any final decision about how it will address the issue of budget neutrality in connection with payments to 340B hospitals. Thus, Plaintiffs are effectively asking the Court to preemptively rule on the legality of hypothetical actions that the agency might (or might not) take on remand. That cart-before-the-horse approach is contrary to the ordinary process in APA cases, which is for “the agency to decide in the first instance how best to provide relief.” *Shands Jacksonville*, 959 F.3d at 1118. If Plaintiffs are dissatisfied with the agency’s decision on remand, they “of course . . . [would] have the option to seek review on the ground

that” the agency’s remedy “w[as] ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *Id.*

Plaintiffs’ approach is also contrary to the limits on the Court’s authority to review agency action. Under the APA, the Court may review only “final agency action[s].” 5 U.S.C. § 704. A final agency action is one which marks the consummation of the agency’s decision-making process and is “one by which rights or obligations have been determined, or from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 178 (1997). A *potential* remedy is not final agency action. The mere possibility that the agency might adopt a budget neutral remedy does not mark the consummation of the agency’s decision-making process, and it is not an action that determines rights or obligations, nor would any legal consequences flow from it. *Cf. Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 42 (D.D.C. 2008) (plaintiff’s request to “assess[] the adequacy of the remand proceedings as they progress . . . comes perilously close to involving the Court in reviewing non-final agency actions”).

Judge Kollar-Kotelly addressed a very similar dispute in *Citrus HMA, LLC v. Becerra*, No. 20-707, 2022 U.S. Dist. LEXIS 65832 (D.D.C. Apr. 8, 2022). There, the court found that HHS had improperly reimbursed certain hospitals located in urban areas at lower rates than rural hospitals in the same states. *Id.* at *2-3. On the issue of remedies, the plaintiffs sought an order vacating the challenged policy and directing the agency to recalculate the plaintiffs’ payments in a particular manner. *Id.* at *26-27. But the court agreed with the government that remand without vacatur was appropriate. *Id.* at *27. In particular, the court noted the parties’ disagreement over the impact of budget neutrality requirements on the recalculation of payments, but determined that “the Secretary should address the appropriate adjustment of Plaintiffs’ reimbursement rates in the

first instance[.]” *Id.* at *28. Here, too, the agency should have the first opportunity to address the extent to which budget neutrality principles may require offsetting payments to 340B hospitals.

2. Plaintiffs’ Arguments Do Not Undermine the Court’s Prior Conclusion That the Agency Should Consider Budget Neutrality Issues First

Nothing in Plaintiffs’ Motion casts doubt on the Court’s conclusion that questions about whether the agency’s reimbursements must be budget neutral should be addressed by the agency in the first instance. Mem. Op., ECF No. 50, at 15 n.15.

Plaintiffs first argue that the question of whether budget neutrality permits or requires HHS to recoup payments to other providers is distinct from the issue of payments due to Plaintiffs. Mot. at 7. But HHS’s reduction of the 340B hospital reimbursement rates and the corresponding increases to other OPSS payments were inextricably linked. Mem. Op., ECF No. 50, at 18-19. And given that there are multiple potential ways for HHS to correct payments for the claims at issue, *see supra* at 10-12, it makes sense for HHS to consider the potential impact of budget neutrality at the same time that it determines the appropriate remedy.

Next, Plaintiffs contend that “the text of the OPSS statute makes clear that budget neutrality applies prospectively—not retrospectively.” Mot. at 7. But the Court has already explained that the D.C. Circuit has suggested otherwise. Mem. Op., ECF No. 50, at 19-20. Specifically, in *Amgen, Inc. v. Smith*, the D.C. Circuit stated that while “[p]ayments to hospitals are made on a prospective basis, . . . given the length of time that review of individual payment determinations could take, review could result in the *retroactive ordering* of payment adjustments after hospitals have already received their payments for the year.” 357 F.3d 103, 112 (D.C. Cir. 2004) (emphasis added). It further explained that “both the pass-through and equitable adjustments to payment rates are subject to a budget neutrality requirement under § (t)(2)(E), such that judicially mandated

changes in one [OPPS] payment rate would affect the aggregate impact of the Secretary's decisions *by requiring offsets elsewhere[.]*" *Id.* (emphasis added).

Moreover, Plaintiffs' textual argument ignores that the agency may respond to the Supreme Court's ruling by promulgating a rule that provides additional compensation to Plaintiffs. And if that rule is retroactive,³ then the increase in payment could be considered an "[a]dditional expenditure[] resulting from this paragraph . . . [that] shall be taken into account" in determining the payment rate for all other covered items and services in a budget neutral fashion. 42 U.S.C. § 1395l(t)(14)(H). Pursuant to 42 U.S.C. § 1395l(t)(14)(H), any adjustments made by the Secretary to payment rates using the formula outlined in subparagraph (t)(14)(A)(iii) are subject to the general budget neutrality requirements outlined in subparagraph (t)(9) (subject to an express exception for 2004 and 2005).⁴

Next, Plaintiff describes three instances in which it claims the agency fixed prior errors without recouping prior payments to achieve budget neutrality. Mot. at 10. None of those instances show that the government lacks the authority to recoup payments to achieve budget

³ Although there is generally a presumption against the retroactive application of agency rules, *see Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 207, 215, (1988), Congress has authorized retroactive rulemaking under the Medicare statute if "the Secretary determines that (i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest." 42 U.S.C. § 1395hh(e)(1)(A).

⁴ *H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. v. Azar*, 324 F. Supp. 3d 1 (D.D.C. 2018), cited by Plaintiffs (Mot. at 9), does not hold that HHS may not recoup payments to maintain budget neutrality. On the contrary, the decision suggested that budget neutrality concerns could be cured by the agency through recoupment. 324 F. Supp. 3d at 15 ("While the most logical way to carry out the statute's budget-neutrality mandate is to decrease rates prospectively for the upcoming year, nothing says that is the only way."); *see also id.* at 17 n.5 ("The adjustment could theoretically have a retroactive impact on private parties, if the government decided that budget neutrality demanded clawing back funds to other hospitals for the services rendered during the 2011 calendar year.").

neutrality, should it choose to do so. At most, they suggest only that the government has some degree of discretion on the issue.

First, Plaintiffs note that HHS authorized a purported retroactive adjustment to approximately ten rural hospitals in the 2007 OPPS Rule without making any offsetting recoupments. Mot. at 10. But the agency's decision, in the context of the rural hospital adjustment, about whether to upend millions of claims decisions and recoup funds from thousands of hospitals to offset additional payments to only approximately ten rural hospitals—while incurring significant administrative costs to do so—does not preclude the agency from determining that, here, a retroactive upward adjustment in the neighborhood of \$1.6 billion for five calendar years and numerous hospitals would require an offsetting recoupment to satisfy the statutory budget neutrality requirement. *Cf. H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 16 (distinguishing that case, which concerned a single adjustment applied to 11 cancer hospitals, from cases involving adjustments to prospective payment rates).

Second, Plaintiffs note that the agency did not recoup payments after it determined that OPPS payment rates were inflated in certain years but instead removed the inflationary effect going forward. Mot. at 10. But unlike here, that situation involved a statutory provision authorizing the agency to adjust the conversion factor for subsequent years if it makes a particular determination about spending in prior years. *See* 80 Fed. Reg. 70,298, 70,353 (Nov. 13, 2015). That is far different from here, where the agency adopted a particular policy and directly related to that policy was a corresponding change to the OPPS conversion factor in the very year the policy was adopted.

Third, Plaintiffs point to a regulation that applies where a judicial decision reverses an agency denial of a hospital's wage data revision request, 42 C.F.R. § 412.64(*l*), and argue that the

agency can revise a wage index without making corresponding changes for budget neutrality. Mot. at 10. The regulation that Plaintiffs cite governs wage-index adjustments for particular hospitals (which might be necessary, for example, if a Medicare contractor incorrectly performs some wage calculations). In that situation, it would make little sense for the agency to reopen all wage index determinations to make a likely *de minimis* change to maintain budget neutrality. Nothing in 42 C.F.R. § 412.64(l) forecloses the agency from making a different determination when the impact of the judicial determination is far larger, with billions of dollars of public money at stake.

3. The Court Should Not Prohibit HHS From Offsetting Payments to Achieve Budget Neutrality

Finally, Plaintiffs go so far as to request the Court award affirmative relief on the issue of budget neutrality. Specifically, they propose that the Court order Defendants not to offset their remedial payments “through other changes designed to achieve budget neutrality[.]” Prop. Order at 1; *see also* Mot. at 11. But there is no claim in this case challenging any offsets that the agency might, in the future, decide to make. Nor could there be, as Plaintiffs clearly lack standing to challenge a mere potential agency action. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (“the plaintiff must have suffered an injury in fact . . . which is (a) concrete and particularized . . . and (b) actual or imminent, not conjectural or hypothetical”). And, as discussed above, there is presently no final agency action regarding budget neutrality for the Court to review. *See supra* at 14. Given that the agency has not yet had an opportunity to fashion a remedy, the Court should not preemptively prohibit the government from recouping certain payments from providers, especially considering the many billions of dollars at issue here and the extraordinary financial impact such a ruling would have on the federal government. *See Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1111 (D.C. Cir. 2014) (“The question whether the Secretary could reach the same result through adjudication was not before the district court; therefore the court erred by directing

the Secretary how to calculate the hospitals' reimbursements, rather than just remanding after identifying the error.").

D. The Court Should Remand Without Vacatur

Instead of issuing an injunction, the Court should remand to allow the agency to take appropriate remedial action following receipt of public comment that will inform the agency's decision-making on these complex issues. Indeed, that process is already underway. As discussed above, HHS has already published an NPRM to revise the OPSS for 2023, and that NPRM seeks "public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022[.]" 87 Fed. Reg. 44505, 44649. The public comment period ended on September 13, 2022. *Id.* at 2. The Court should remand and allow the agency to complete that administrative process, instead of cutting that process short and imposing Plaintiffs' preferred remedy, with significant consequences for numerous hospitals that are not parties to this case.⁵

The remand, moreover, should be without vacatur. Notably, Plaintiffs' Motion does not actually seek vacatur, perhaps because the Court already determined that vacatur of the 2018 and 2019 OPSS Rules was "not [w]arranted," and Plaintiffs did not appeal or seek reconsideration of that decision. Mem. Op., ECF No. 50, at 16.⁶ Applying the standard articulated in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146 (D.C. Cir. 1993), the Court determined

⁵ Plaintiffs express concern that the agency, on remand, might not implement a remedy that provides appropriate compensation. Mot. at 6. Such speculation is not a basis for the Court to issue an injunction instead of remanding. As noted above, if Plaintiffs are dissatisfied with the agency's decision on remand, they "of course . . . [would] have the option to seek review on the ground that" the agency's remedy "w[as] 'arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.'" *Shands Jacksonville*, 959 F.3d at 1118.

⁶ Plaintiffs' separate motion relating to year 2022, by contrast, does seek vacatur of a portion of the 2022 OPSS Rule. See ECF No. 67.

that the first factor weighed in favor of vacatur, but that the second factor weighed against it because “vacatur would likely be highly disruptive[.]” Mem. Op., ECF No. 50, at 18.

Defendants submit that that concern remains true today and that remand without vacatur continues to be appropriate. The portions of the rules addressing payment for drugs purchased under the 340B Program cannot be severed from the rest of the OPPS rates set forth in the 2018-2022 OPPS rules. “Severance and affirmance of a portion of an administrative regulation is improper if there is ‘substantial doubt’ that the agency would have adopted the severed portion on its own.” *Davis County Solid Waste Mgmt. & Energy Recovery Special Serv. Dist. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997). Here, the impropriety of severance is clear, given that when the agency reduced the payment rate for drugs purchased through the 340B Program, it increased the payment rate for other items and services covered by the OPPS rules. Mem. Op., ECF No. 50, at 18-19. As a result, if the Court were to vacate the portion of the rules dealing with the payment rate for drugs purchased through the 340B Program, it would have to vacate other rates set by the OPPS rules in their entirety. The Court would then either “order the Secretary to reinstate the rule previously in effect—the 2017 OPPS Rule—or leave it to the Secretary to issue new rules.” *Id.* at 18.

As the Court previously explained, either scenario would raise “potentially serious administrative problems.” *Id.* In particular, the “uncertainty surrounding th[e budget neutrality] issue all but guarantees its resolution would be highly disruptive[.]” *Id.* at 20. “Relatedly, the presumption against retroactive rulemaking would also complicate vacatur, given that vacatur would force the Secretary to retroactively issue rules[.]” *Id.* Vacatur is not appropriate under these circumstances. *See Shands Jacksonville*, 959 F.3d at 1121 (affirming district court decision not to vacate Medicare payment rule where the plaintiffs’ preferred remedy would “create a significant administrative burden” on the agency); *Citrus*, 2022 U.S. Dist. LEXIS 65832, at *27-28 (remanding to HHS without vacating Medicare payment rule where vacatur would raise

complicated administrative questions relating to budget neutrality); *Am. Great Lakes Ports Ass'n v. Zukunft*, 301 F. Supp. 3d 99, 100-01, 104 (D.D.C. 2018) (declining to vacate a rule issued by the Coast Guard regarding the “rates that international shippers must pay to maritime pilots on the waters of the Great Lakes” due to the disruptive consequences of vacatur).

E. The Court Should Not Retain Jurisdiction

Lastly, the Court should reject Plaintiffs’ request that the Court “retain jurisdiction over the case and require monthly status reports[.]” Mot. at 13. While the Court “has the discretion to retain jurisdiction over a case pending completion of a remand,” “this discretion is typically reserved for cases alleging unreasonable delay of agency action or failure to comply with a statutory deadline, or for cases involving a history of agency noncompliance.” Mem. Op., ECF No. 59, at 3-4 (quoting *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008)). This case involves no such claim.

Plaintiffs do not argue otherwise, but instead maintain that part of the reason the Court previously declined to retain jurisdiction no longer applies. Mot. at 13-14. Specifically, Plaintiffs note that the Court previously found that “‘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.’” *Id.* at 13. Of course, if the Court remands this case and either side wants to appeal aspects of that remand order, retention of oversight over remand would again call into question the finality of the remand order, so the Court’s prior reasoning is still very relevant. Moreover, Plaintiffs ignore the Court’s prior findings regarding the factors described in *Baystate*. Mem. Op., ECF No. 59, at 4. In any event, “the agency is entitled to the presumption that it will discharge its

duties in good faith.” *See, e.g., Empire Health Found. v. Becerra*, No. 20-2149, 2022 U.S. Dist. LEXIS 22503, at *16 (D.D.C. Feb. 8, 2022). Retention of jurisdiction is thus unwarranted.

CONCLUSION

The Court should remand this matter to the agency without vacatur, and permit the agency to determine in the first instance what remedial measures are appropriate. The Court should deny Plaintiffs’ other remedial requests. If the Court grants any of Plaintiffs’ remedial requests, then Defendants respectfully request that the Court stay the order to afford the Solicitor General sufficient time to decide whether to pursue appeal. *See* 28 C.F.R. § 0.20(b); 28 U.S.C. § 2107(b).

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ERIC B. BECKENHAUER
Assistant Branch Director
Federal Programs Branch

/s/ Joshua Kolsky
JOSHUA KOLSKY
Trial Attorney
D.C. Bar No. 993430
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW Washington, DC 20005
Tel.: (202) 305-7664
Fax: (202) 616-8470
E-mail: joshua.kolsky@usdoj.gov

Attorneys for Defendants

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

American Hospital Association, *et al.*,

Plaintiffs,

–v–

Xavier Becerra, Secretary of Health and Human
Services, *et al.*,

Defendants.

Case No. 1:18-cv-2084 (RC)

ORDER

Upon consideration of Plaintiffs’ Motion to Hold Unlawful and Remedy Defendants’ Past Underpayment of 340B Drugs, Defendants’ response thereto, and the entire record herein, it is hereby **ORDERED** that Plaintiffs’ Motion is **DENIED**.

It is **SO ORDERED** this ____ day of _____, 202__.

United States District Judge