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 VACATE THE UNLAWFUL PORTION OF THE 2022 OPPS RULE

INTRODUCTION

Upon remand of this case, Plaintiffs immediately filed a pair of motions. The first asks the Court to (1) "hold unlawful the 2020, 2021, and 2022 OPPS Rules" and (2) "order Defendants to promptly . . . [pay Plaintiffs] the difference between what they were paid and ASP plus 6%." ECF No. 69 at 1-2. The second motion, at issue here, seeks overlapping relief on an even more accelerated timeframe: it asks the Court to (1) "expeditiously . . . vacate the portion of the 2022 OPPS rule that carves out 340B drugs from the general payment rate for separately payable drugs" and (2) "order Defendants to immediately begin reimbursing 340B drugs at ASP plus 6% for the remainder of 2022." Motion to Vacate the Unlawful Portion of the 2022 OPPS Rule ("Motion"), ECF No. 67 at 2. But the agency is already in the midst of seeking public comment on the best remedy for these very calendar years. And the vacatur and injunctive relief that Plaintiffs seek would not only be inappropriate, but highly disruptive, as the Court previously found in rejecting the same request for the 2018 and 2019 calendar years. *See* Mem. Op., ECF No. 50. 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). Accordingly, the proper remedy for the remainder of 2022 (and for the earlier time periods at issue in this case) is to remand the matter to the agency. That remand, moreover, should be without vacatur.

Notably, Plaintiffs' Motion entirely ignores the budget neutrality principles that the Court has already found to weigh against vacatur. When the agency decreased the payment rate for drugs purchased through the 340B program, it correspondingly increased the payment for other items and services covered under the Outpatient Prospective Payment System ("OPPS"). Abruptly increasing payments for drugs purchased through the 340B Program for the remainder of 2022 would raise complicated questions regarding budget neutrality.

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. As noted, 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[.]"[1] The public comment period is ongoing and will end on September 13, 2022. *Id*. at 2. The Court should allow the agency to complete that administrative process and devise a solution for all of the calendar years at issue, given the potential for disruption in the immense and complex system that has been entrusted to the agency to operate.

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

[1] https://public-inspection.federalregister.gov/2022-15372.pdf, at 352.

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 OPPS 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 OPPS 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 OPPS for 2023.[2] That NPRM explains that, based on the Supreme Court's decision in this matter, the agency anticipates applying a rate of ASP plus six percent to 340B hospitals for 2023, and adjusting the OPPS 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 is ongoing and will end on September 13, 2022. *Id*. at 2.

ARGUMENT

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 calendar year 2022. Mot. at 5. Defendants therefore do not oppose Plaintiffs' motion to the extent it seeks a ruling that the 2022 OPPS Rule is unlawful insofar as it varies the reimbursement rate for 340B hospitals from ASP plus six percent absent a survey of hospitals' acquisition costs.

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[2] https://public-inspection.federalregister.gov/2022-15372.pdf.

Defendants do oppose Plaintiffs' requested remedy. At the outset, Plaintiffs' request for injunctive relief is inconsistent with decades of settled precedent, which Plaintiffs 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").

Although there are some limited instances in which courts order injunctive relief in APA cases, such relief is not warranted here. For one thing, Plaintiffs have not even attempted to demonstrate why injunctive relief would be appropriate under the relevant legal standard. *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." *Ramirez*, 568 F. Supp. 3d at 21 (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 156-57 (2010)). These factors, which Plaintiffs' Motion ignores, do not support injunctive relief here. In particular, Plaintiffs cannot establish irreparable harm 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 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."). And Plaintiffs make no attempt to explain how the equities could favor a remedy that would give them a windfall, such as by paying them higher reimbursement rates for 340B-acquired drugs while also allowing them to retain the inflated conversion factor. Plaintiffs' failure to address these factors is reason enough to deny their Motion. *See, e.g.*, *CC1 Ltd. P'ship v. NLRB*, 898 F.3d 26, 35 (2018) (arguments not raised in opening brief are forfeited).

Injunctive relief is also inappropriate for many of the reasons the Court previously identified when it denied Plaintiffs' prior, similar requests. 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." Mem. Op., ECF No. 50 at 15 (quoting *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013)); *see also N. Air Cargo v. USPS*, 674 F.3d 852, 861 (D.C. Cir. 2012) ("When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal."). Here, there are

multiple ways for HHS to resolve underpayments for 2022. For example, the 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.

Similarly, here, a prospective rate increase would be an option for 2022, yet Plaintiffs' Motion seeks to foreclose that option and eliminate the agency's discretion to craft an appropriate remedy. Plaintiffs' Motion, therefore, is inconsistent with the "'heightened deference' that courts are to accord 'the Secretary's interpretation of a 'complex and highly technical regulatory program' such as Medicare.'" *Id.* at 1118; *see also id*. ("[I]t is ordinarily 'the prerogative of the agency to decide in the first instance how best to provide relief.'").

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. § 1395*l*(t)(14)(A)(iii)(I), § 1395*l*(t)(14)(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 underpayment, if any, to remedy. Plaintiffs' Motion, however, would foreclose the possibility of conducting a survey.

Plaintiffs' Motion also fails to even acknowledge, much less resolve, the significant budget neutrality concerns that would be implicated by an order requiring HHS to increase 340B hospital reimbursement rates mid-year—concerns that prompted the Court to reject their prior request for the same relief. As the Court explained, "[i]n general, OPPS payments must remain budget neutral," and such "[b]udget neutrality dictates that any increase in spending on certain aspects of Medicare Part B must be offset by decreases elsewhere in the program." Mem. Op., ECF No. 50, at 18; *see also* 42 U.S.C. § 1395*l*(t)(9)(B) (stating that OPPS rate "adjustments for a year may not cause the estimated amount of expenditures . . . for the year to increase or decrease from the estimated amount of expenditures . . . that would have been made if the adjustments had not been made"). In other words, HHS's reduction of the 340B hospital reimbursement rates for 2022 and the corresponding increases to other OPPS payments were inextricably linked. Plaintiffs' proposal that the Court "order Defendants to immediately begin reimbursing 340B drugs at ASP plus 6% for the remainder of 2022," Mot. at 2, entirely fails to account for such budget neutrality concerns. It is precisely the purpose of a remand for the agency to consider questions such as this. Indeed, the Supreme Court implicitly acknowledged the need to resolve complicated questions relating to budget neutrality when it discussed the parties' respective positions on that issue, explained that it

"need not address potential remedies," and remanded the case for further proceedings. *AHA*, 142 S. Ct. at 1903, 1906.

Plaintiffs alternatively propose that the Court "order Defendants to take action, such as through an interim final rule, providing that within 30 days of the Court's Order, and for the remainder of 2022, 340B drugs will be reimbursed at a rate of ASP plus 6%[.]" Mot. at 7. Putting aside the significant practical difficulties associated with such a rulemaking (the agency has limited resources and those resources are already occupied with the ongoing OPPS rulemaking for 2023), that proposal "disregard[s] the separation of powers mandated by the Constitution." *Org. for Competitive Mkts. v. U.S. Dep't of Agric.*, 912 F.3d 455, 458 n.3 (8th Cir. 2018) (declining to order agency to issue rules and regulations). Moreover, it suffers from the same problems as Plaintiffs' first proposal. It would eliminate the agency's discretion to formulate a reimbursement solution, by foreclosing options such as adjusting reimbursement rates in future years, and it likewise fails to account for budget neutrality concerns. Plaintiffs may argue that the interim final rule could itself address budget neutrality by decreasing other OPPS rates to account for the higher 340B reimbursement rates. But an interim final rule, by definition, would not provide disaffected hospitals an opportunity to comment on such changes to their reimbursement rates. The government would almost certainly face litigation if it were to abruptly adjust hospital reimbursement rates mid-year without first providing an opportunity for public comment.

Plaintiffs contend that vacatur is appropriate under *Allied Signal, Inc. v. United States Nuclear Regulatory Commission*, 988 F.2d 146 (D.C. Cir. 1993). Mot. at 6. But that argument is no more persuasive now than it was when Plaintiffs raised it, unsuccessfully, earlier in the litigation. As the Court has already explained with respect to the 2018 and 2019 OPPS Rules, "vacatur would likely be highly disruptive" because increasing 340B reimbursement rates would

raise "potentially serious administrative problems." Mem. Op., ECF No. 50, at 18. The same would be true if the Court were to vacate the 2022 OPPS Rule mid-year. 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 HMA, LLC v. Becerra*, No. 20-707, 2022 U.S. Dist. LEXIS 65832, at *27-28 (D.D.C. Apr. 8, 2022) (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, 100-101, 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).

Plaintiffs do not deny the disruptive consequences of vacatur but suggest the Court should ignore those consequences because Defendants did not take unspecified "steps to prepare for the possibility that their policy would be held unlawful mid-year[.]" Mot. at 6. Plaintiffs specifically criticize Defendants for "issu[ing] the 2022 OPPS Rule" when Defendants "knew that the Supreme Court had granted certiorari in this case and would issue a decision in 2022 that could invalidate the reimbursement cut for 340B drugs." *Id*. at 3. That argument is baffling. The mere "*possibility* that the rate cut would ultimately be held unlawful," *id*. (emphasis added), did not preclude the agency from issuing the 2022 OPPS Rule. The 2018 and 2019 OPPS Rules had, of course, been sustained by the D.C. Circuit. And it is not clear what "contingency plan" Plaintiffs believe the agency could have developed prior to even knowing what the Supreme Court's decision would be, much less knowing the specific reasoning underlying that decision. *Id*. As to Plaintiffs' assertion that the agency did not "act promptly in the wake of the Supreme Court's ruling," Mot. at 6, the

agency swiftly responded to the Supreme Court's June 15 decision by addressing that decision in its July rulemaking, explaining that it expected to change the reimbursement rates for 2023 because of the decision, and seeking public comment on potential remedies for 2018 to 2022 calendar years in light of the decision.

Plaintiffs also cite *American Hospital Association v. Azar*, No. 18-2841, 2019 U.S. Dist. LEXIS 181244 (D.D.C. Oct. 21, 2019), where the court vacated a rule and remanded the case to HHS. But that decision only illustrates why vacatur is inappropriate here. There, the court found that HHS had exceeded its statutory authority when it reduced a particular reimbursement rate. *Id*. at *1-2. The court determined that vacatur of the rate reduction was appropriate because it could be severed from the rest of the final rule. *Id*. at *5-7. As the court explained, "the reduced rate . . . 'operate[d] entirely independently' of the underlying OPPS reimbursement scheme and was 'not in any way 'intertwined'' with CMS's obligation to review and set those underlying OPPS reimbursement rates." *Id*. at *7. Here, in contrast, CMS's decisions regarding payment rates for 340B drugs in the 2022 Rule were directly connected to its decisions regarding payment rates for non-drug services in the 2022 Rule, as the Court has already found with respect to 2018 and 2019. *See* Mem. Op., ECF No. 50, at 19. Accordingly, vacating the reduction in 340B reimbursement rates would run afoul of the principle that "[s]everance 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 Cty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir 1997); *Am. Petroleum Inst. v. EPA*, 862 F.3d 50, 72 (D.C. Cir. 2017) ("Thus we have severed provisions when 'they operate[d] entirely independently of one another.'").

Instead of foreclosing the agency's discretion and mandating a particular remedy, the Court should remand without vacatur 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 OPPS for 2023, and that NPRM seeks "public comments on the best way to craft any proposed, potential remedies affecting calendar years 2018-2022[.]"[3] The public comment period is ongoing and will end on September 13, 2022. *Id*. at 2. The Court should 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.

Lastly, to put this Motion in perspective, it bears emphasis that it pertains only to a small sliver of the overall time periods challenged in this action. This case now includes challenges to five separate calendar years and yet the instant Motion seeks relief only "for the remainder of 2022," Mot. at 2, which at best (assuming the Court rules immediately) is less than five months. It makes little sense to isolate a small fraction of the overall calendar years at issue and impose a remedy limited to that time period. Instead, the best approach is for the agency to consider all of the calendar years at issue (2018 through 2022) together and implement a solution for all of those years. Indeed, Plaintiffs have already filed a separate motion seeking a remedy for 2018 to 2022. Mot. to Hold Unlawful and Remedy Defs' Past Underpayment of 340B Drugs, ECF No. 69. Defendants submit that the outcome of that motion should control for all of the years at issue, including the remainder of 2022.

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[3] https://public-inspection.federalregister.gov/2022-15372.pdf, at 352.

CONCLUSION

The Court should remand this matter to the agency without vacatur and permit the agency to determine what remedial measures are appropriate. The Court should deny Plaintiffs' other remedial requests.

Respectfully submitted,

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