

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

AMERICAN HOSPITAL	:	
ASSOCIATION, <i>et al.</i> ,	:	
	:	
Plaintiffs,	:	Civil Action No.: 18-2084 (RC)
	:	
v.	:	Re Document No.: 67
	:	
XAVIER BECERRA, in his official capacity	:	
as the secretary of Health and Human Services,	:	
<i>et al.</i> ,	:	
	:	
Defendants.	:	

ORDER

GRANTING PLAINTIFFS' MOTION TO VACATE

For the reasons stated in the Court's Memorandum Opinion separately and contemporaneously issued, Plaintiffs' motion to vacate (ECF No. 67) is **GRANTED**. It is hereby:

ORDERED that the drug reimbursement rate for 340B hospitals in the 2022 OPPS Rule is hereby **VACATED** with respect to its prospective application.

SO ORDERED.

Dated: September 28, 2022

RUDOLPH CONTRERAS
United States District Judge

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as the secretary of Health and Human Services,	:	
<i>et al.</i> ,	:	
	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING PLAINTIFFS’ MOTION TO VACATE

I. INTRODUCTION

As part of its duty to administer the Medicare statute, the Department of Health and Human Services (“HHS”) establishes annual rates reimbursing hospitals for outpatient services and drugs through the Outpatient Prospective Payment System (“OPPS”). In *American Hospital Association v. Becerra*, 142 S. Ct. 1896 (2022), the Supreme Court unanimously held that HHS exceeded its statutory authority by varying its 2018 and 2019 OPPS reimbursement rates for a particular group of hospitals—“340B hospitals”—without having first conducted a statutorily mandated survey of hospitals’ acquisition costs. *Id.* at 1899. The case has returned to this Court to decide the issue of remedies. Plaintiffs, a group of hospital associations and non-profit hospitals, now ask the Court to vacate the *prospective* portion of the 340B reimbursement rate in the 2022 OPPS Rule—in other words, to “forbid Defendants from underpaying 340B claims for

the remainder of 2022.” Pls.’ Mot. to Vacate (“Mot.”) at 2, ECF No. 67.¹ For the reasons stated below, the prospective portion of the 2022 reimbursement rate shall be vacated because it is defective and because vacating this portion of the 2022 OPPS Rule will not cause substantial disruption. Moreover, the Court finds that injunctive relief is not necessary because vacatur will immediately revert the 340B reimbursement rate to the default rate.

II. BACKGROUND

This is the Court’s fourth opinion in this case, so it will assume familiarity with the facts and provide only an overview of the litigation’s posture. This Court previously held that HHS exceeded its statutory authority by reducing the 2018 Medicare reimbursement rate for 340B hospitals without having first conducted a statutorily mandated survey. *See Am. Hosp. Assoc. v. Azar (“AHA I”)*, 348 F. Supp. 3d 62, 67–72 (D.D.C. 2018). After considering supplemental briefing on the issue of remedies, the Court decided to remand the 2018 and 2019 OPPS Rules to HHS without vacatur for the agency to take a “first crack at crafting appropriate remedial measures.” *Am. Hosp. Ass’n v. Azar (“AHA II”)*, 385 F. Supp. 3d 1, 3–4 (D.D.C. 2019). The Court reasoned that although vacatur was a possibility, remand was the better option given the “potentially serious administrative problems” and disruption that could result from vacatur. *Id.* at 13.

¹ The hospital association Plaintiffs are the American Hospital Association (“AHA”), the Association of American Medical Colleges (“AAMC”), and America’s Essential Hospitals (“AEH”). *See* 2d Suppl. Compl. ¶¶ 8–13, ECF No. 66-1. The non-profit hospital Plaintiffs are the Henry Ford Health System (“Henry Ford Hospital”), Northern Light Health (“Northern Light”), and AdventHealth Hendersonville (“AdventHealth,” formerly called Park Ridge Health). *See id.* ¶¶ 14–22. Defendant Becerra has since replaced Defendant Azar as the Secretary of Health and Human Services. The Court will refer to HHS and the Secretary interchangeably.

The Court then entered final judgment to facilitate expeditious review of the case on the merits in the D.C. Circuit. *Am. Hosp. Ass'n v. Azar* (“*AHA III*”), No. 18-cv-2084, 2019 WL 3037306, at *1 (D.D.C. July 10, 2019). The D.C. Circuit reversed. *Am. Hosp. Ass'n v. Azar*, 967 F.3d 818, 820 (D.C. Cir. 2020). In a divided opinion, it held that “HHS’s decision to lower drug reimbursement rates for 340B hospitals rests on a reasonable interpretation of the Medicare statute.” *Id.* The D.C. Circuit first found that HHS was entitled to *Chevron* deference on its interpretation of the Medicare provision. *Id.* at 828. It then held that the Secretary was authorized to vary the 340B reimbursement rate under his “general adjustment authority.” *Id.* at 834. Unsatisfied with this result, Plaintiffs sought review by the Supreme Court, which granted certiorari. *Am. Hosp. Ass'n v. Becerra*, 141 S. Ct. 2883 (2021).

The Supreme Court reversed. In a unanimous opinion, the Supreme Court agreed with Plaintiffs’ slightly revised version of its argument that HHS had no authority to fix a different reimbursement rate for 340B hospitals without first conducting a statutorily mandated survey. *Becerra*, 142 S. Ct. at 1906; *see* 42 U.S.C. § 1395l(t)(14)(A)(iii)(I) (giving the Secretary authority to “vary” reimbursement rates “by hospital group” only if he relies on “hospital acquisition cost survey data”). The Supreme Court chose not to “address potential remedies,” *Becerra*, 142 S. Ct. at 1903, instead remanding the case to the D.C. Circuit, which in turn remanded it to this Court, *Am. Hosp. Ass'n v. Becerra*, No. 19-5048, 2022 WL 3061709, at *1 (D.C. Cir. Aug. 3, 2022).

On remand to this Court, Plaintiffs filed two motions. The first motion seeks to vacate the portion of the 340B reimbursement rate in the 2022 OPPS Rule that is still in effect for the remainder of this year. ECF No. 67. The second motion, by contrast, looks backward: it seeks to remedy all of HHS’s underpayments to 340B hospitals under the unlawful reimbursement

rates in OPPS Rules 2018–2022. ECF No. 69. Plaintiffs and HHS briefed the first motion on an expedited schedule, and it is now ripe for review. ECF No. 68; Min. Order (Aug. 4, 2022). At a later time, the Court will issue a separate opinion resolving the second motion.²

III. ANALYSIS

Plaintiffs’ first motion raises two questions. First, the Court must determine whether to vacate the 340B reimbursement rate for the remainder of this year. Second, if yes, the Court must decide whether it is necessary to grant relief in the form of an injunction. The answer to the first question is yes; the answer to the second is no.

A. Vacatur is Warranted

“When a rule is contrary to law, the ‘ordinary practice is to vacate’ it.” *Am. Bankers Ass’n v. Nat’l Credit Union Admin.*, 934 F.3d 649, 673 (D.C. Cir. 2019) (citation omitted). Even though “vacatur is the normal remedy,” the D.C. Circuit has stated that “a court [may] remand without vacating the agency’s action in limited circumstances.” *Am. Great Lakes Ports Ass’n v. Schultz*, 962 F.3d 510, 518 (D.C. Cir. 2020) (quoting *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1110 (D.C. Cir. 2014)). “To determine whether to remand without vacatur, this court considers first, the seriousness of the [action’s] deficiencies, and, second, the likely disruptive consequences of vacatur.” *Id.* at 518–19 (cleaned up) (quoting *Allied-Signal, Inc. v. Nuclear Regulatory Comm’n*, 988 F.2d 146, 150–51 (D.C. Cir. 1993)). “Because vacatur is the default remedy . . . defendants bear the burden to prove that vacatur is unnecessary.” *Friends of the*

² The Federation of American Hospitals filed an amicus brief on behalf of “more than 1,000” non-340B hospitals, arguing that “the Medicare statute forecloses any attempt to offset remedial payments through retroactive recoupment of funds from non-340B hospitals.” See Amicus Curiae Br. at 1, 3, ECF No. 74. This issue is not relevant to the Court’s resolution of Plaintiffs’ first motion, so the Court will not address it in this Opinion.

Earth v. Haaland, 583 F. Supp. 3d 113, 156 n.29 (D.D.C. 2022) (quoting *Nat'l Parks Conservation Ass'n v. Semonite*, 422 F. Supp. 3d 92, 99 (D.D.C. 2019)).

Here, HHS admits that the 340B reimbursement rate in the 2022 OPPS Rule is unlawful. *See* Defs.' Opp'n to Pls.' Mot. to Vacate ("Opp'n") at 5, ECF No. 71 ("Defendants therefore do not oppose Plaintiffs' motion to the extent it seeks a ruling that the 2022 OPPS Rule is unlawful . . ."). The Supreme Court said as much when it held that "the [2003 Medicare] statute does not grant HHS authority to vary the reimbursement rates by hospital group unless HHS has conducted the required survey of hospitals' acquisition costs." *Becerra*, 142 S. Ct. at 1904. Thus, the only remaining question is whether the Court should vacate the 340B reimbursement rate in the 2022 OPPS Rule with respect to its application for the rest of this year.³

The first *Allied-Signal* factor plainly weighs in favor of vacatur. The deficiency in the 2022 Rule is serious. The Court previously observed that the Secretary "patently violated the Medicare Act's text" and "no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner." *AHA II*, 385 F. Supp. 3d at 12–13. That is just as true now: since that decision, the Supreme Court has confirmed that "[b]ecause HHS did not conduct a survey of hospitals' acquisition costs, HHS acted unlawfully by reducing the reimbursement rates for 340B hospitals." *Becerra*, 142 S. Ct. at 1904.

The second *Allied-Signal* factor—whether vacatur would cause substantial disruption—also weighs in favor of vacatur. HHS, who bears the "burden to prove that vacatur is unnecessary," advances primarily two arguments on this front. *Friends of the Earth*, 583 F.

³ Neither side addressed whether Plaintiffs satisfied their administrative exhaustion requirements to challenge the 2022 OPPS Rule in court. *See* 42 U.S.C. § 405(g).

Supp. 3d at 158. First, HHS relies heavily on this Court’s ruling in *AHA II* which granted remand without vacatur to argue that the same result should occur here. Second, HHS argues that vacatur is disruptive because it implicates issues of budget neutrality. Neither argument is persuasive.

First, HHS’s reliance on *AHA II* is misplaced. Unlike the situation here, *AHA II* did not specifically discuss the disruption associated with vacatur of a reimbursement rate that still had *prospective* effect. But that is precisely—and solely—what Plaintiffs’ motion seeks here: vacatur of the 340B rate for the remainder of 2022. *See Schultz*, 962 F.3d at 519 (“[A] quintessential disruptive consequence arises when an agency cannot easily *unravel a past transaction* in order to impose a new outcome.” (emphasis added)). This Court in *AHA II* focused on the disruption that vacatur would cause for the agency in providing relief for *past* underpayments. *See AHA II*, 385 F. Supp. 3d at 13 (noting it would be a “expensive and time-consuming prospect” for HHS to “recoup certain payments” and “already processed claims”); *id.* at 14 (identifying problems associated with “retroactive rulemaking”); *id.* n.19 (“[R]emand without vacatur will allow the agency more flexibility to determine the least disruptive means of correcting its underpayments to Plaintiffs[.]”). Even in that context, *AHA II* noted that vacatur was “a close question” and that the *Allied-Signal* factors weighed in favor of remand only “ever so slightly.” *Id.* at 12. Thus, many of the concerns that animated the *AHA II* findings of disruption simply do not apply here.⁴

⁴ HHS relies on cases where courts remanded agency actions without vacating them, but those cases are inapposite because they did not involve agency actions that still had *prospective* effect at the time of the courts’ decisions. *See Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 250 (D.D.C. 2015) (remanding fiscal year 2014 rule); *Citrus HMA, LLC v. Becerra*, No. 20-cv-707, 2022 WL 1062990, at *10 (D.D.C. Apr. 8, 2022) (remanding fiscal year 2020 rule); *Am. Great Lakes Ports Ass’n v. Zukunft*, 301 F. Supp. 3d 99, 100 (D.D.C. 2018) (remanding 2016 rule).

According to HHS, however, Plaintiffs necessarily sought relief in *AHA II* from the prospective portion of 2019 OPPS Rule. Opp’n at 3. True, Plaintiffs did seek relief from the prospective portion of the 2019 Rule in their motion for permanent injunction of the 2019 Rule. Pls.’ Mot. Permanent Inj. at 3–4, ECF No. 35; *see also* Pls.’ Opp’n to Gov’t’s Mot. to Dismiss and Reply in Support of Mot. for Permanent Inj. at 1–2, ECF No. 45. But Plaintiffs’ *remedies* briefing did not discuss vacating the prospective portion of the 2019 Rule, because by that briefing deadline, they had not yet filed a supplemental complaint incorporating a challenge to the 2019 Rule. Accordingly, *AHA II* did not focus its remedies discussion on whether vacatur would be appropriate for the prospective portion of an unlawful reimbursement rate. *See AHA II*, 385 F. Supp. 3d at 10 n.14 (“Plaintiffs’ remedies briefing does not specifically discuss the 2019 OPPS Rule.”). And in any event, *AHA II* did not consider that particular issue in isolation, which is before the Court now for the first time.

Second, HHS argues that vacatur implicates thorny issues concerning the agency’s duty to maintain budget neutrality. As *AHA II* observed, “[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.” *Id.* at 13 (citation omitted). But *AHA II* also noted that “[b]udget neutrality is likely to cause disruption *regardless of whether the Court vacates* the 2018 and 2019 OPPS Rules,” and it considered budget neutrality concerns insofar as “remand without vacatur will allow the agency more flexibility to determine the least disruptive means of *correcting its underpayments to Plaintiffs[.]*” *Id.* at 14 n.19 (emphases added). By contrast, HHS is attempting to use budget neutrality now as a shield to justify *ongoing and continuing* application of an unlawful reimbursement rate that no amount of reasoning can rehabilitate on remand. *See* Pls.’ Reply in Support of Pls.’ Mot. to Vacate (“Reply”) at 7–9, ECF No. 75. HHS has not cited a

single case, nor is the Court aware of any, that gives the agency this power. The Court is troubled that HHS appears to rely on budget neutrality as a license “to continue violating the law for the remainder of the year and make up for it later.” Reply at 4. The D.C. Circuit has cautioned against “remanding without vacatur” when the “circumstances would give the [agency] incentive” to act “first” and then “review[] later.” *Env’t Def. Fund v. FERC*, 2 F.4th 953, 976 (D.C. Cir. 2021) (citation omitted). HHS should not be allowed to continue its unlawful 340B reimbursements for the remainder of the year just because it promises to fix the problem later.

The Court recognizes that HHS’s budget will be unbalanced if it must immediately start to pay 340B hospitals their proper due for the remainder of 2022. But that disruption would be minimal, because HHS admits that vacating the 340B reimbursement rate for the remainder of 2022 would account for “only [] a small sliver of the overall time periods challenged in this action.” Opp’n at 13. HHS’s own “perspective” of the relief Plaintiffs seek in this motion demonstrates that vacatur would not cause substantial disruption. Indeed, HHS already began taking steps to prepare for potential budget issues this year as a result of the Supreme Court’s holding in *Becerra*. See Opp’n at 12 (HHS is currently “seeking public comment on potential remedies for . . . [the] 2022 calendar year[]”). Furthermore, HHS has announced in its proposed rulemaking for the 2023 OPPS Rule its intent to pay 340B hospitals the proper reimbursement rate for the 2023 year. See Opp’n at 5 (2023 proposed rule “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[.]” (citing <https://public-inspection.federalregister.gov/2022-15372.pdf>)). In short, the Court finds that any disruption that will be caused by vacating the

prospective portion of the 2022 OPSS Rule’s 340B reimbursement rate does not rise to the level of justifying remand without vacatur.

B. No Injunction Is Necessary

Having established that it will vacate the prospective portion of the 340B reimbursement rate in the 2022 Rule, the Court also determines that no injunction is needed to effectuate Plaintiffs’ requested relief. Plaintiffs claim that “[i]f the Court vacates [Defendants’] unlawful policy of carving out 340B drugs as an ‘exception’ from the generally applicable payment rate for separately payable drugs under the OPSS Rule, then 340B drugs would *immediately* become subject to the generally applicable payment rate of ASP plus 6% for the remainder of the year.” Mot. at 6 (emphasis added).⁵ But HHS seems to think that an injunction is required for 340B reimbursement rates to return to the default reimbursement rate—that is, average sales price (“ASP”) plus 6%. *See* Opp’n at 6 (characterizing Plaintiffs’ request as “for injunctive relief” and arguing Plaintiffs have not met the standard for injunctive relief).

When an agency action is unlawful, an injunction is required only when plaintiffs seek “some agency action beyond that which was vacated.” *Friends of the Earth*, 583 F. Supp. 3d at 162 (citing *WildEarth Guardians v. United States Bureau of Land Mgmt.*, 870 F.3d 1222, 1240 (10th Cir. 2017)). In other words, when vacatur “leav[es] the precise consequences of vacatur uncertain,” the court’s additional demands on the agency must meet “the traditional four-factor test” for injunctive relief. *Standing Rock Sioux Tribe v. United States Army Corps of Engineers*,

⁵ Elsewhere, however, Plaintiffs appear to ask for an injunction. *See, e.g.*, Mot. at 4 (asking the court to “enjoin Defendants from underpaying 340B claims for the remainder of 2022”). Because the Court finds that an injunction is unnecessary, it will simply vacate the prospective portion of the 340B reimbursement rate in the 2022 OPSS Rule.

985 F.3d 1032, 1054 (D.C. Cir. 2021) (quoting *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 158 (2010)).

Here, “there is nothing to be enjoined” because the consequences of vacatur are certain. *Friends of the Earth*, 583 F. Supp. 3d at 162. By vacating the prospective portion of the 340B reimbursement rate, it is “naturally implied” that the 340B reimbursement rate will automatically revert to the default reimbursement rate under the Medicare statute. *Standing Rock*, 985 F.3d at 1054. This result is evident from the regulatory scheme governing OPPS reimbursement rates, which characterizes the 340B reimbursement rate as an exception to the default reimbursement rate. Mot. at 6; Reply at 11. The 2022 OPPS Rule provides that HHS will “continue [its] payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals, *with the exception of 340B-acquired drugs*, at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default)” and that HHS would “pay for separately payable nonpass-through drugs acquired with a 340B discount at a rate of ASP minus 22.5 percent (as described in section V.B.6).” 86 Fed. Reg. 63,458, 63,640 (Nov. 16, 2021) (emphasis added). Vacating the prospective portion of the 340B reimbursement rate excises this exception such that HHS shall “pay for separately payable drugs and biologicals at ASP+6 percent in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).” *Id.* (alterations by Court). By vacating the exception, the general reimbursement rate would automatically apply to 340B hospital groups, without additional court-mandated action. *Cf. Ass’n of Am. Railroads v. United States Dep’t of Transportation*, 896 F.3d 539, 549 (D.C. Cir. 2018) (“[T]o the extent possible, courts ‘limit the solution to the problem, severing any problematic portions while leaving the remainder intact.’” (citation omitted)). Therefore, vacatur without injunction is appropriate to provide Plaintiffs their desired relief.

HHS does not object to Plaintiffs’ characterization of the 340B reimbursement rate as an exception to the general rule. Instead, it leans on the doctrine 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 Cnty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (citation omitted); Opp’n at 12. HHS argues that it would not have adopted the specific payment rates for *non-drug* services in the 2022 OPPTS Rule had it known that 340B hospitals would be subject to the default drug reimbursement rate. Opp’n at 12. But HHS’s counterfactual of how the agency would have tweaked reimbursement rates (presumably to meet budget neutrality) misses the point, because the relevant question is whether HHS would have enacted the default reimbursement rate had it known that it could not enact a lower rate for 340B hospitals. *Cf. Ass’n. of Am. Railroads*, 896 F.3d at 549 (severability analysis asks “whether the legislature would prefer not to have B if it could not have A as well” (citation omitted)).⁶ On that question, the answer is clear. “For more than a decade,” HHS *did* “use[] the same reimbursement rates for all hospitals” and “never varied the reimbursement rates by hospital group.” *Becerra*, 142 S. Ct. at 1900. Not only has the agency adopted this regulatory scheme in the past, it plans to do so in the future in light of the Supreme Court’s decision in *Becerra*. *See* Opp’n at 5 (2023 proposed rule “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[.]”). *Cf. Davis*, 108 F.3d at 1459–1460 (severing EPA’s “1995 standards only as they apply to small MWC units and cement kilns” because “[t]here is simply no basis for believing that the EPA would not have adopted the standards applicable to large

⁶ HHS’s narrow interpretation of the severability standard, on the other hand, would imply that no rate could ever be vacated, no matter how unlawful, because the agency would have employed slightly different and offsetting rates in a counterfactual world.

MWC units without the standards for small MWC units”). Therefore, vacatur, without injunction, is appropriate.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** Plaintiffs’ Motion to Vacate (ECF No. 67). The drug reimbursement rate for 340B hospitals in the 2022 OPPS Rule is hereby **VACATED** with respect to its prospective application. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: September 28, 2022

RUDOLPH CONTRERAS
United States District Judge