

2023 WL 143337

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United States District Court, District of Columbia.

AMERICAN HOSPITAL
ASSOCIATION, et al., Plaintiffs,

v.

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

Civil Action No. 18-2084 (RC)

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Filed 01/10/2023



Re Document No.: 69

MEMORANDUM OPINION

RUDOLPH CONTRERAS United States District Judge


**GRANTING IN PART AND DENYING IN
PART PLAINTIFFS' MOTION TO HOLD
UNLAWFUL AND REMEDY DEFENDANTS'
PAST UNDERPAYMENTS OF 340B DRUGS**



I. INTRODUCTION

*1 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. Upon return to this Court to decide the issue of remedies, Plaintiffs, a group of hospital associations and non-profit hospitals, filed two separate motions. On September 28, 2022, the Court granted Plaintiffs' first motion and vacated the prospective portion of the 340B reimbursement rate in the 2022 OPPS Rule. *Am. Hosp. Ass'n v. Becerra* ("AHA I"), No. 18-cv-2084, 2022 WL 4534617, at *5 (D.D.C.

Sept. 28, 2022). Now before the Court is Plaintiffs' second motion, which looks backwards and seeks to remedy all of HHS's underpayments to 340B hospitals under the unlawful reimbursement rates in OPPS Rules 2018–2022. Pls.' Mot. to Hold Unlawful & Remedy Defs.' Past Underpayment of 340B Drugs ("Mot."), ECF No. 69.¹ For the reasons described below, the Court concludes that HHS's 340B reimbursement rates in the 2018–2022 OPPS Rules are unlawful. But rather than vacate those rules, it will remand without vacatur to give the agency the opportunity to remediate its underpayments.

II. BACKGROUND

This is the Court's fifth 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. Ass'n 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.

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). A divided panel 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).

*2 The Supreme Court reversed. In a unanimous opinion, the Supreme Court agreed with Plaintiffs' slightly revised version of their 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 moved to supplement their complaint to challenge the 340B reimbursement rates in the 2020, 2021, and 2022 OPSS Rules, and the Court granted this request. *See* Pls.' Mot. for Leave to File 2d Suppl. Compl., ECF No. 66; Min. Order (Aug. 4, 2022).² At the same time, Plaintiffs filed two motions. The first motion sought to vacate the portion of the 340B reimbursement rate in the 2022 OPSS Rule that was still in effect for the remainder of this year. *See* Pls.' Mot. Vacate Unlawful Portion of 2022 OPS Rule, ECF No. 67. The Court granted this motion in *AHA IV*. *See AHA IV*, 2022 WL 4534617, at *5. The Court began with the observation that “HHS admit[ted] that the 340B reimbursement rate in the 2022 OPSS Rule is unlawful.” *Id.* at *2. Turning to the question of remedies, the Court found that the *Allied-Signal* factors both weighed in favor of vacatur because “[t]he deficiency in the 2022 Rule is serious” and “disruption would be minimal.” *Id.* at *3–4. The Court emphasized that unlike *AHA II*'s finding of significant disruption associated with “relief for *past* underpayments,” vacatur of a reimbursement rate with only “*prospective* effect” would not upset settled transactions and would have a relatively minimal impact on budget neutrality. *Id.* at *3 (emphases in original); *see also id.* (“[A] quintessential disruptive consequence arises when an agency cannot easily *unravel a past transaction* in order to impose a new outcome.” (emphasis in original) (quoting *Am. Great Lakes Ports Ass'n v. Schultz* (“[Am. Great Lakes IP](#)”), 962 F.3d 510, 519 (D.C. Cir. 2020))).

Now before the Court is Plaintiffs' second motion, which seeks to remedy all of HHS's underpayments to 340B hospitals under the unlawful reimbursement rates in OPSS

Rules 2018–2022. ECF No. 69. The second motion is ripe for decision.³

III. ANALYSIS

The parties do not dispute that the 2018–2022 OPSS Rules are unlawful. Defs.' Opp'n to Pls.' Mot. to Hold Unlawful & Remedy Defs.' Past Underpayment of 340B Drugs (“Opp'n”) at 6, ECF No. 76; Pls.' Reply in Support of Pls.' Mot. to Hold Unlawful & Remedy Defs.' Past Underpayment of 340B Drugs (“Reply”) at 4, ECF No. 77.⁴ So the Court must confront the same question as it did in *AHA II*: “how to ‘unscramble the egg’ ” and “determin[e] the proper remedy ... given Medicare's complexity.” *AHA II*, 385 F. Supp. 3d at 10. Here, as in *AHA II*, Plaintiffs seek injunctive relief. *See* Mot. at 6 (seeking court order for “prompt and full repayment of the difference between what 340B hospitals were paid and ASP plus 6%”). Defendants once again seek remand without vacatur. Opp'n at 1. Like *AHA II*, the Court concludes that remand without vacatur is most appropriate here.

A. Remand is Appropriate

*3 Remand, rather than an injunction, is the better course. “[W]hen 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.” *AHA II*, 385 F. Supp. 3d at 11 (quoting [N. Air Cargo v. USPS](#), 674 F.3d 852, 861 (D.C. Cir. 2012)). Thus, when a plaintiff brings an APA claim “to set aside an unlawful agency action ... it is the prerogative of the agency to decide in the first instance how best to provide relief.” [Bennett v. Donovan](#), 703 F.3d 582, 589 (D.C. Cir. 2013) (citing [N. Air Cargo](#), 674 F.3d at 861). Indeed, in certain circumstances, “to order the agency to take specific actions is reversible error.” *Flaherty v. Pritzker*, 17 F. Supp. 3d 52, 57 (D.D.C. 2014) (citing [Cnty. of Los Angeles v. Shalala](#), 192 F.3d 1005 (D.C. Cir. 1999)). If the plaintiffs are “dissatisfied with [the agency's] remedy [on remand], they would always have the option to seek review” of that remedy under the APA. [Bennett](#), 703 F.3d at 589 (citing [5 U.S.C. § 706\(2\)\(A\)](#)); *accord Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1118 (D.C. Cir. 2020).

It is true that “[i]njunctive relief is typically appropriate when there is only one rational course for the [a]gency to follow upon remand.” *AHA II*, 385 F. Supp. 3d at 11 (cleaned up). Seizing this standard, Plaintiffs argue that the Supreme Court’s holding in *Becerra* “dictates a single possible remedy”: “repaying those hospitals that were unlawfully underpaid, from 2018 to the present, the difference between what they were paid and ASP plus 6%.” Mot. at 2, 4. But the Supreme Court expressly declined to address the issue of remedies. See *Becerra*, 142 S. Ct. at 1903 (“At this stage, we need not address potential remedies.”). And this Court has already identified several potential remedies that the parties previously put on the table. See *AHA II*, 385 F. Supp. 3d at 11 (“Plaintiffs note that there are multiple ways for HHS to remediate its underpayments, some more complicated than others.”); *id.* (“As the parties’ briefing makes clear, HHS has multiple courses on remand, including Plaintiffs’ proposed mechanism.”); *id.* n.15 (listing examples). Thus, the Court is puzzled by Plaintiffs’ attempt to now characterize the remedial path as providing just one option, and it fails to see what exactly that option is.

To the extent Plaintiffs seek an order commanding HHS to repay each underpaid claim to the penny, that cannot possibly be the only rational choice available to the agency. As Plaintiffs readily acknowledge, HHS could seek to implement a remedy such as a prospective one-time rate increase that *avoids* calculating individual claims. See Reply at 6 (favorably citing *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 959 F.3d 1113, 1120 (D.C. Cir. 2020), which upheld as reasonable the Secretary’s remedy of implementing a “one-year rate increase” that “would not precisely compensate each hospital for payments that were reduced under the [unlawful] Rule”); see also Opp’n at 10 (“[T]here are multiple ways for HHS to resolve the disputed claims ... and not all those methods would pay hospitals ASP plus 6% on a drug-by-drug, claim-by-claim basis.”).

Or perhaps Plaintiffs seek something more basic. To the extent Plaintiffs ask for an order “requiring ‘prompt repayment’ without demanding any specific actions from the agency, Reply at 6, it is unclear what practical effect such an order would achieve. Remand alone would presumably accomplish the same thing. See *AHA II*, 385 F. Supp. 3d at 4 (remanding to the agency “to resolve this issue promptly”); see also *id.* at 12 (noting that the cases Plaintiffs cited showed that agencies remedied problem on remand without court-

ordered injunction); cf. *Black Oak Energy, LLC v. FERC*, 725 F.3d 230, 244 (D.C. Cir. 2013) (remand without vacatur “is not an invitation to do nothing”). Indeed, HHS has already stated in its recently published 2023 Final OPPTS Rule that it “plan[s] to issue a separate proposed rule detailing [its] proposed remedy for CYs 2018 to CY 2022 in advance of the CY 2024 OPPTS/ASC proposed rule.” 2023 OPPTS Final Rule at 71,973. Thus, the Court will follow “the normal course in this jurisdiction under these circumstances: remand.” *AHA II*, 385 F. Supp. 3d at 12.⁵


B. Vacatur is not Warranted




*4 The Court turns next to the question of whether to remand with or without vacatur.⁶ “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 II*, 962 F.3d at 518 (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 Regul. 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 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)).

Recall that *AHA II* concluded that remand without vacatur was appropriate for the 2018 and 2019 OPPTS Rules under the *Allied-Signal* factors because, although the deficiency in the 340B reimbursement rates was “substantial,” “vacatur would likely be highly disruptive.” *AHA II*, 385 F. Supp. 3d at 12–13. Here, the parties do not dispute that the first *Allied-Signal* factor continues to weigh in favor of vacatur, so the Court will focus on the second *Allied-Signal* factor—that is, the potentially disruptive consequences of vacatur. Since *AHA II*, nothing has changed to suggest that vacatur is now the better




option. In fact, because the number of unlawful transactions at issue has increased with the passage of time, the case for remand without vacatur has only grown stronger.



The D.C. Circuit has recently noted that “a quintessential disruptive consequence arises when an agency cannot easily unravel a past transaction in order to impose a new outcome.”

 *Am. Great Lakes II*, 962 F.3d at 519. That is this case. Although *AHA II* already explained in detail the highly disruptive risks that would flow from vacatur in this context, the Court will elaborate on that analysis here. As a matter of law, “[w]hen a court vacates an agency’s rules, the vacatur restores the status quo before the invalid rule took effect[.]”

Am. Great Lakes Ports Ass’n v. Zukunft (“ *Am. Great Lakes I*”), 301 F. Supp. 3d 99, 103 (D.D.C. 2018) (citation omitted), *aff’d sub nom.*  *Am. Great Lakes II*, 962 F.3d 510. Applying that principle here, vacatur would “set aside” the unlawful 340B reimbursement rates (ASP minus 22.5%) in the 2018–2022 OPSS Rules, leaving the default rate from the 2017 OPSS Rule (ASP plus 6%) to take their place and “be deemed operative for the entirety” of 2018–2022.  *Id.* at 104. As *AHA II* explained, “[w]hile those higher rates would address Plaintiffs’ harm, they would raise ... potentially serious administrative problems.” *AHA II*, 385 F. Supp. 3d at 13. Then, as now, these weighty complications warrant remand without vacatur.

One source of this disruption, *AHA II* explained, is HHS’s duty to maintain budget-neutral OPSS payments. According to HHS, “if the Secretary were to retroactively raise the 2018 [through 2022] 340B rates, budget neutrality would require him to retroactively lower the 2018 [through 2022] rates for other Medicare Part B products and services.” *Id.* But “because HHS has already processed claims under the previous rates, the Secretary would potentially be required to recoup certain payments made to providers; an expensive and time-consuming prospect.” *Id.* Plaintiffs argue that budget neutrality has no relevance here, even going so far as to call it a “[r]ed herring[.]” Reply at 2; *see also* Amicus Curiae Br. at 4–11. They claim that “nothing in federal law requires—or even authorizes—[the agency] to retrospectively recoup funds to achieve budget neutrality.” Mot. at 7. HHS, unsurprisingly, disagrees. The parties trade arguments on this issue, just as they did in *AHA II*. *See AHA II*, 385 F. Supp. 3d at 14 (“The parties ... strongly debate whether the Secretary’s remedial rate adjustments must be budget neutral.”).

*5 While *AHA II* expressly declined to resolve this issue, it noted that the D.C. Circuit has “suggested” that HHS’s remedial adjustments must be budget neutral. *Id.* (citing  *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004); *see*  *Amgen*, 357 F.3d at 112 (noting that “judicially mandated changes in one [OPSS] payment rate would affect the aggregate impact of the Secretary’s decisions by requiring offsets elsewhere, and thereby interfere with the Secretary’s ability to ensure budget neutrality in each fiscal year”). Plaintiffs attempt to distinguish *Amgen* by contending that this portion of the opinion is dicta and not based on the text of the relevant budget neutrality provision. Reply at 12. But whether dicta or otherwise, “[a]t this stage, it suffices to say that the uncertainty surrounding this issue all but guarantees its resolution would be highly disruptive” in the event of vacatur. *AHA II*, 385 F. Supp. 3d at 14; *see also Citrus HMA, LLC v. Becerra*, No. 20-cv-707, 2022 WL 1062990, at *10 (D.D.C. Apr. 8, 2022) (observing the parties’ disagreement concerning budget neutrality but remanding to HHS without vacatur because “the Court agrees that the Secretary should address the appropriate adjustment of Plaintiffs’ reimbursement rates in the first instance”); Reply at 15 (acknowledging that “budget neutrality is an extremely complex process”). That uncertainty weighs against vacatur because the second *Allied-Signal* factor only requires HHS to show the “likely,” as opposed to definite, consequences of vacatur.  *Am. Great Lakes II*, 962 F.3d at 518.⁷

As if the prospect of having to recoup over four years’ worth of overpayments were not disruptive enough, there is a risk that HHS may lack authority to recoup these funds *at all* because of the presumption against retroactive rulemaking. Under this presumption, “a statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms.” *AHA II*, 385 F. Supp. 3d at 14 (quoting  *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). Here, this presumption complicates vacatur because “[t]he Secretary may not be able to retroactively adjust 340B payments,” given that it would involve creating a backward-looking rule that attempts to recoup reimbursements that have already been doled out years ago. *Id.* at 15; *see*  *Heartland Reg’l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) (discussing, without resolving, the problem of retroactive rulemaking and concluding that “it [is] sufficient for the purpose of the second *Allied-Signal* factor that vacatur of

the rural location requirement would have raised substantial doubt about HHS's ability to recoup payments it made for years prior to reinstatement of that requirement"). Indeed, Plaintiffs and amicus's position that HHS cannot retroactively recoup the funds, Reply at 14–15; Amicus Curiae Br. at 4–12, suggests that any attempt by HHS to proceed in this fashion "would almost certainly trigger litigation," *AHA II*, 385 F. Supp. 3d at 15. "Remand may allow the agency to avoid the issue altogether." *Id.*

One more consideration favors remand without vacatur: the staggering value and number of transactions at issue. Recall that *AHA II* only had occasion to consider a remedy for the 2018 and 2019 OPSS Rules. This case now involves the 2018, 2019, 2020, 2021, and 2022 OPSS Rules. By some estimates, nearly \$10 billion dollars of underpayments are at stake. *See* 2023 OPSS Final Rule at 71,973 (commentators estimating \$2 billion in 340B drug underpayments per year); *id.* at 71,974 (HHS approximating a \$1.96 billion offset needed in 2023 for 340B drug reimbursements to return to default rate). In addition, vacatur could upset an enormous number of settled transactions that occurred in those years. *Cf.* Def.'s Response to Pls.' Suppl. Notice at 1, ECF No. 84 (noting that OPSS program as a whole "processes more than 100 million claims a year"). "Given the 'complex prospective payment system' at issue here, the Court concludes that vacating the 2018 [through 2022] OPSS Rules would do more harm than good." *AHA II*, 385 F. Supp. 3d at 15 (quoting *Amgen*, 357 F.3d at 112). Therefore, the Court will remand without vacatur.

*6 Finally, the Court declines Plaintiffs' invitation to retain jurisdiction on remand. Courts in this District routinely remand without vacatur while declining to retain jurisdiction. *See, e.g., Citrus*, 2022 WL 1062990, at *10; *H. Lee Moffitt Cancer Ctr. and Rsch. Inst. Hosp. v. Azar*, 324 F. Supp. 3d 1, 19 (D.D.C. 2018); *Am. Great Lakes I*, 301 F. Supp. 3d at 105. Although the Court retained jurisdiction on remand in *AHA II*, it subsequently granted HHS's motion for reconsideration and changed course in *AHA III*. *See AHA III*, 2019 WL 3037306, at *2. As the Court explained, the discretion to retain jurisdiction on remand "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." *Id.* (citing *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d

37, 41 (D.D.C. 2008); *Cobell v. Norton*, 240 F.3d 1081, 1109 (D.C. Cir. 2001)); *accord Empire Health Found. v. Becerra*, No. 20-cv-2149, 2022 WL 370559, at *5 (D.D.C. Feb. 8, 2022). Plaintiffs claim that this case is suitable for the Court to retain jurisdiction because of an established pattern of "extreme agency delay," but the Court does not see it that way. Reply at 17 (citation omitted). Following the Court's instruction in *AHA II* to consider the matter on remand, HHS chose instead (as was its right) to appeal to the D.C. Circuit, and, having won there, to defend its position in the Supreme Court. Following the Supreme Court's decision in June of this year holding the 340B reimbursement rates unlawful, this Court has yet to give the agency an opportunity to remediate its underpayments. *Cf. Baystate*, 587 F. Supp. 2d at 41 n.5 ("The Court does not consider the years-long administrative litigation ... to indicate recalcitrance and resistance to fulfilling legal duties, but instead to reflect the kind of hard-fought litigation that regularly occurs in cases involving programmatic relief and multi-million dollar payments."). Moreover, HHS has indicated that it plans to issue a detailed proposed remedy prior to issuing the 2024 OPSS Rule. 2023 OPSS Final Rule at 71,973; Def.'s Response to Pls.' Suppl. Notice at 1–2 ("[HHS] has committed to announcing [a remedy for claims submitted 2018 through September 27, 2022] through special notice-and-comment rulemaking, which it intends to complete before the 2024 OPSS rulemaking cycle is complete."). Although the Court declines to retain jurisdiction, it expects that HHS will act promptly to remediate its underpayments.

IV. CONCLUSION

For the foregoing reasons, the Court grants in part and denies in part Plaintiffs' Motion to Hold Unlawful and Remedy Defendants' Past Underpayments of 340B Drugs (ECF No. 69). The matter is remanded to HHS for further proceedings consistent with this Opinion. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

All Citations

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Footnotes

- 1 According to HHS, “claims for 340B-acquired drugs paid after [this Court’s] September 28, 2022 ruling are paid at the default rate (generally ASP plus 6 percent.)” 87 Fed. Reg. 71,748, 71,973 (Nov. 23, 2022) (“2023 OPPS Final Rule”). Thus, the Court considers a remedy for the 2022 OPPS Rule in this Opinion only with respect to the portion of that rule preceding September 28, 2022.
- 2 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 (“Henry Ford Hospital”), Northern Light Health (“Northern Light”), and AdventHealth Hendersonville (“AdventHealth,” formerly called Park Ridge Health). See *id.* ¶¶ 14–22.
- 3 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.” Amicus Curiae Br. at 1, 3, ECF No. 74. The Court will consider this amicus brief in its decision.
- 4 Neither side addressed whether Plaintiffs satisfied their administrative exhaustion requirements to challenge the 2020–2022 OPPS Rules in court. See 42 U.S.C. § 405(g); *AHA I*, 348 F. Supp. 3d at 76 (finding that Plaintiffs administratively exhausted challenge to 2018 OPPS Rule); *AHA II*, 385 F. Supp. 3d at 7 (finding that Plaintiffs administratively exhausted challenge to 2019 OPPS Rule).
- 5 The Court also denies Plaintiffs’ request for an injunction because they fail to describe how they satisfy the four-factor test for injunctive relief. See *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 158 (2010) (holding that before issuing injunctive relief, “a court must determine that an injunction *should* issue under the traditional four-factor test” (emphasis in original)); Opp’n at 7–8.
- 6 Plaintiffs’ opening brief did not expressly request vacatur, but their reply brief clarified that they seek it. Reply at 9–10. Given the importance of this issue, the Court will consider it on the merits.
- 7 For that reason, it is unnecessary for the Court to decide whether HHS’s remedial rate adjustments must be budget neutral. See *AHA II*, 385 F. Supp. 3d at 15 n.20 (observing that the Court “need not decide” budget neutrality challenges “at this stage.”). Because the agency has yet to offer a remedy on remand (much less defend it in court), a premature ruling on this issue is unwarranted. See *Pub. Serv. Elec. & Gas Co. v. FERC*, 783 F.3d 1270, 1274 (D.C. Cir. 2015) (“[T]he oldest and most consistent thread in the federal law of justiciability is that the federal courts will not give advisory opinions.” (citation omitted)); Opp’n at 18.