UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN HOSPITAL ASSOCIATION, *et al.*,	:	
Plaintiffs,	:	Civil Action No.: 18-2084 (RC)
v.	:	Re Document Nos.: 35, 40, 42
ALEX M. AZAR II, United States Secretary of Health and Human Services, *et al.*,	:	
Defendants.	:	

MEMORANDUM OPINION

GRANTING IN PART PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION; REMANDING THE 2018 AND 2019 OPPS RULES TO HHS

I. INTRODUCTION

This Court previously held that the Department of Health and Human Services ("HHS") exceeded its statutory authority when it reduced the 2018 Medicare reimbursement rate for certain pharmaceutical drugs—those covered by the "340B Program"—by nearly 30%. In that decision, the Court asked the parties to provide supplemental briefing regarding the appropriate remedy. That briefing is now ripe for the Court's consideration. Plaintiffs, a group of hospital associations and non-profit hospitals,[1] have also filed a supplemental complaint raising a new claim. They contend that HHS once again exceeded its statutory authority when it implemented

[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* Suppl. Compl. ¶¶ 5–10, ECF No. 39. The non-profit hospital Plaintiffs are the Henry Ford Health System ("Henry Ford Hospital"), Northern Light Health ("Northern Light"), and Park Ridge Health ("Park Ridge"). *See id.* ¶¶ 11–19.

the same 340B reimbursement rate for 2019 that the Court held was unlawfully implemented in 2018.[2]

For the reasons stated below, the Court concludes that HHS's 2019 340B reimbursement rate is unlawful, for the same reasons that the 2018 rate was unlawful. The Court also concludes that, despite the fatal flaw in the agency's rate adjustments, vacating HHS's 2018 and 2019 rules is not the best course of action, given the havoc vacatur may wreak on Medicare's administration. Rather, the Court will remand the two rules to the agency, giving it the first crack at crafting appropriate remedial measures. The Court expects HHS to resolve this issue promptly.

II. BACKGROUND

This Court's most recent opinion contains a detailed discussion of this case's background and procedural history, and the relevant statutes and regulations. *See Am. Hosp. Assoc. v. Azar ("AHA")*, 348 F. Supp. 3d 62, 66–72 (D.D.C. 2018). The Court will briefly summarize the relevant background here.

Medicare is a federal health insurance program for the elderly and disabled, established by Title XVIII of the Social Security Act. *See* 42 U.S.C. §§ 1395–1395*lll*.[3] Medicare Part A provides coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B provides supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k. HHS's Outpatient Prospective Payment System ("OPPS"), which directly reimburses hospitals for outpatient services and pharmaceutical drugs

[2] Plaintiffs assert their claims against both HHS and the Secretary of Health and Human Services. *See* Suppl. Compl. ¶¶ 20–21. The Court will refer to HHS and the Secretary interchangeably.

[3] These provisions are commonly known as the "Medicare Act." The Court will refer to them as such.

provided to Medicare beneficiaries, is a component of Medicare Part B. *See id*. at 1395*l*(t). OPPS requires "payments for outpatient hospital care to be made based on predetermined rates." *Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Under this system, the Secretary—through the Centers for Medicare and Medicaid Services ("CMS")—sets annual OPPS reimbursement rates prospectively, before a given year, rather than retroactively based on covered hospitals' actual costs during that year.[4]

Medicare Part B reimburses, among other products and services, "specified covered outpatient drugs" ("SCODs") provided by hospitals to Medicare beneficiaries. 42 U.S.C. § 1395*l*(t)(14)(A). SCODS are a subset of "separately payable drugs," which are not bundled with other Medicare Part B outpatient services, and are therefore reimbursed on a drug-by-drug basis. *See id*. § 1395*l*(t)(14)(B). Congress has authorized two potential methodologies for setting SCOD rates. First, if the Secretary has certain "hospital acquisition cost survey data," he must set the reimbursement rate for each SCOD according to "the *average acquisition cost* for the drug for that year . . . as determined by the Secretary taking into account" the survey data. *Id.* § 1395*l*(t)(14)(A)(iii)(I) (emphasis added). Second, if the survey data is not available, each SCOD's reimbursement rate must be set equal to "the *average [sales] price* [("ASP")] for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id*. § 1395*l*(t)(14)(A)(iii)(II) (emphasis added). Section 1395w-3a, in turn, provides that a given drug's default reimbursement rate is the average sales price ("ASP") of the drug plus 6%.[5]

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[4] CMS is a component of HHS and is overseen by the Secretary. *See* HHS Organizational Chart, HHS (Nov. 14, 2018), https://www.hhs.gov/about/agencies/orgchart/index.html.

[5] While subsection (t)(14)(A)(iii)(II) provides two additional bases for calculating reimbursement rates—section 1395u(o) and section 1395w-3b—both parties agree that the

The Secretary applies the same methodologies used to set SCOD reimbursement rates to set rates for separately payable drugs covered by the "340B Program."[6] *See* Veterans Health Care Act of 1992, Pub L. No. 102-585, § 602, 106 Stat. 4943, 4967–71. The 340B Program "imposes ceilings on prices drug manufacturers may charge for medications sold to specified health care facilities." *Astra USA, Inc. v. Santa Clara Cty.*, 563 U.S. 110, 113 (2011); *see also* 42 U.S.C. § 256b(a)(1)–(2).[7] The statutory provisions that establish those price ceilings are independent from the statutory provisions that establish Medicare reimbursement rates. Put another way, the 340B Program caps the prices that eligible providers pay for covered drugs, but Medicare Part B sets the reimbursement rates those providers receive for prescribing covered drugs to Medicare beneficiaries. Until recently, there was a significant spread between 340B prices and Medicare reimbursement rates. 340B Program participants could purchase drugs at steeply discounted rates under the Program, then seek reimbursement for those purchases at the

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default rate for purposes of the drugs at issue here is the rate established by section 1395w-3a. *See* Defs.' Mot. to Dismiss at 6, ECF No. 14; Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 3–4, ECF No. 2-1; Medicare Program: Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,501 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419) (acknowledging ASP plus 6% as the "statutory benchmark").

[6] Not all 340B drugs qualify as SCODs, to which the payment methodologies of § 1395*l*(t)(14)(A) expressly apply. The Secretary, however, "applies these statutory payment methodologies to *all* separately payable drugs, even those that are *not* SCODS." Defs.' Mot. to Dismiss at 6 n.1, ECF No. 6 (citing Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,383 (Nov. 15, 2012) (codified at 42 C.F.R. pt. 419)); *see also* 82 Fed. Reg. at 52,509 (stating that the rate reduction will apply to "separately payable Part B drugs . . . that are acquired through the 340B Program"). The methodology at issue here thus applies to all 340B drugs. This "is a policy choice rather than a statutory requirement." Defs.' Mot. to Dismiss at 6 n.1 (quoting 77 Fed. Reg. at 68,383).

[7] The Program is intended to enable providers "to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 12 (1992); *see also* 82 Fed. Reg. at 52,493 & 52,493 n.18.

higher Medicare Part B rates established by OPPS. The Secretary's attempt to narrow the spread triggered this litigation.

In mid-2017, the Secretary proposed reducing reimbursement rates for SCODs and other 340B drugs, from ASP plus 6% to ASP minus 22.5%. Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 33,558, 33,634 (Jul. 20, 2017) (codified at 42 C.F.R. pt. 419). The Secretary asserted that this change was necessary to "make Medicare payment for separately payable drugs more aligned with the resources expended by hospitals to acquire such drugs[,] while recognizing the intent of the 340B program to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care." *Id.* at 33,633.

The Secretary's statutory authority to reduce the 2018 340B rate was limited by the data available to him. Because he did not "have hospital acquisition cost data for 340B drugs," 82 Fed. Reg. at 33,634, he could not invoke his express authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) to set rates according to the drugs' average acquisition costs. Instead, he invoked subsection (t)(14)(A)(iii)(II), which allows him to set rates according to the drugs' average sales prices, "as calculated and adjusted by the Secretary as necessary." 82 Fed. Reg. at 33,634. The Secretary proposed to "adjust the applicable payment rate as necessary" for separately payable 340B drugs, "to ASP minus 22.5[%]." *Id.* According to the Secretary, the adjustment was necessary because ASP minus 22.5% was the average 340B discount estimated by the Medicare Payment Advisory Commission ("MedPAC"), and thus "better represents the average acquisition cost for [340B] drugs and biologicals." *Id.* Plaintiffs objected to this adjustment, but the Secretary rejected their objections and adopted the proposal. *See* Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment

Systems and Quality Reporting Programs ("2018 OPPS Rule"), 82 Fed. Reg. 52,356, 52,362 (Nov. 13, 2017) (codified at 42 C.F.R. pt. 419). HHS reimbursed 340B drugs at ASP minus 22.5% throughout 2018.

Having failed to defeat the 2018 340B rate adjustment during the notice and comment period, Plaintiffs challenged the 2018 OPPS Rule in this Court. *See AHA*, 348 F. Supp. 3d at 71–72. They argued that the Secretary exceeded his statutory authority in setting the 2018 340B rate, in violation of the Administrative Procedure Act ("APA") and the Social Security Act. *See id.* at 71. This Court agreed. It held that the Secretary violated subsection (t)(14)(A)(iii)(II)'s plain text when he invoked that provision to "adjust" 340B rates downward by 30%, based not on the drugs' average sales prices—as dictated by the statutory text—but on the drugs' estimated acquisition costs. *See id.* at 79–83. The Court ordered the parties to provide supplemental briefing on the proper remedy. *See id.* at 86.

The Secretary has continued to apply the same 340B rate in 2019. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs ("2019 OPPS Rule"), 83 Fed. Reg. 58,818, 58,979 (Nov. 21, 2018) (codified at 42 C.F.R. pt. 419). And in adopting that rate, the Secretary incorporated by reference his rationale for adopting the 2018 340B rate, the rationale that this Court later held was contrary to law. *See id.* at 58,981 (referring commenters to the Secretary's "detailed response regarding [his] statutory authority to require payment reductions for [340B drugs] in the CY 2018 OPPS/ASC final rule").

Plaintiffs have filed a supplemental complaint, *see* Suppl. Compl., ECF No. 39, and moved to permanently enjoin the 2019 OPPS Rule, *see* Pls.' Mot. Permanent Inj. Covering 2019 OPPS Rule ("Pls.' Mot. Inj."), ECF No. 35. That motion, and the parties' remedies briefing, is

now ripe for the Court's review. The Court will first consider Plaintiffs' motion to enjoin the 2019 OPPS Rule, then the parties' remedies briefing. It grants Plaintiffs' motion in part, and remands both the 2018 and 2019 OPPS Rules to HHS, giving the Secretary the first crack at crafting an appropriate remedy.

III. MOTION FOR PERMANENT INJUNCTION

Rather than fully briefing Plaintiffs' motion to enjoin the 2019 OPPS Rule, the parties have elected to incorporate by reference their arguments regarding the 2018 OPPS Rule. [8] Plaintiffs proffer that "[f]or all of the reasons that the Court has already articulated with respect to the 2018 OPPS Rule, the 2019 OPPS Rule is *ultra vires* and unlawful."[9] Pls.' Mot. Inj. at 2. Defendants respond that their arguments for denying Plaintiffs' challenge to the 2018 OPPS Rule "provide ample bases for rejecting" Plaintiffs' challenge to the 2019 OPPS Rule. Defs.' Opp'n Pls.' Mot. Inj. at 1, ECF No. 42. Recognizing that the Court "rejected those arguments in the context of the 2018 OPPS Rule," Defendants "respectfully request that the Court reconsider its conclusion." *Id.* at 2. The Court declines Defendants' invitation. It enjoins the 2019 OPPS Rule for the same reason that it enjoined the 2018 OPPS Rule. In the interest of thoroughness, the Court will briefly summarize that reasoning.

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[8] In evaluating Plaintiffs' challenge to the 2018 OPPS Rule, the Court consolidated the parties' pleading-stage briefing with a decision on the merits. *See AHA*, 348 F. Supp. 3d at 83–85. The Court does the same here. This case raises pure questions of law that do not turn on the administrative record or any other facts that may emerge at the summary judgment stage. *See id.* Proceeding to summary judgment, rather than reaching a decision now, would thus be redundant and unnecessary. *See Marshall Cty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993). Neither party contests this approach.

[9] Plaintiffs' challenge is grounded in the APA. The APA provides for judicial review of a "final agency action for which there is no other adequate remedy in a court[,]" 5 U.S.C. § 704, except when "statutes preclude judicial review" or the "agency action is committed to agency discretion by law[,]" *id.* § 701(a). The APA permits a court to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A).

First, Plaintiffs have sufficiently exhausted their administrative remedies, such that they may challenge the 2019 OPPS Rule in federal court. To seek judicial review, a plaintiff challenging a Medicare-related agency action must satisfy two requirements established by 42 U.S.C. § 405(g). *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12–15 (2000). First, a jurisdictional, non-waivable "requirement that a claim for benefits shall have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Second, a non-jurisdictional "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id*. This second requirement may be waived by the agency or a court. *See id*. at 330. Together, the two requirements serve the practical purpose of "assur[ing] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes." *Ill. Council*, 529 U.S. at 13.

Plaintiffs satisfied § 405(g)'s first, non-waivable requirement when Henry Ford Hospital presented HHS with two claims for reimbursement for 340B drugs prescribed under the 2019 OPPS Rule. *See* ECF Nos. 34–1 & 34-2. In response, HHS dutifully applied the 2019 340B reimbursement rate challenged by Plaintiffs: ASP minus 22.5%.[10] *Id.* Defendants do not contest that Henry Ford Hospital's 2019 claims satisfy § 405(g)'s presentment requirement.

Plaintiffs need not satisfy § 405(g)'s second requirement, that they fully exhaust the administrative process, because exhaustion would be futile. As this Court previously noted, plaintiffs need not exhaust their administrative remedies when "(1) the issue raised is entirely

[10] Henry Ford Hospital technically presented its claims to a Medicare administrative contractor (also known as a "fiscal intermediary"), which processes reimbursements on behalf of HHS. *See* 42 C.F.R. § 424.32. "If dissatisfied with the contractor's initial determination, the hospital then may pursue within HHS various other avenues for redetermination, reconsideration, hearings, and appeals." *Amgen*, 895 F.3d at 824 (citing 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904); *see also* Pls.' Mem. Supp. Mot. Prelim. & Permanent Inj. at 11, ECF No. 2-1 (describing the Secretary's four-level administrative appeal process).

collateral to a claim for payment; (2) plaintiffs show they would be irreparably injured were the exhaustion requirement enforced against them; [or] (3) exhaustion would be futile." *AHA*, 348 F. Supp. 3d at 75 (alteration in original) (quoting *Triad at Jeffersonville I, LLC v. Leavitt,* 563 F. Supp. 2d 1, 16 (D.D.C. 2008)); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In such circumstances, a "district court may, in its discretion, excuse exhaustion if 'the litigant's interests in immediate judicial review outweigh the government's interests in the efficiency or administrative autonomy that the exhaustion doctrine is designed to further.'" *Avocados Plus Inc. v. Veneman,* 370 F.3d 1243, 1247 (D.C. Cir. 2004) (quoting *McCarthy v. Madigan,* 503 U.S. 140, 146 (1992)). More specifically, the court must consider whether judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record. *See Tataranowicz*, 959 F.2d at 275 (citing *Weinberger v. Salfi*, 422 U.S. 749, 765 (1975)).

As with Plaintiffs' challenge to the 2018 OPPS Rule, *see AHA*, 348 F. Supp. 3d at 75–76, it would be futile for Plaintiffs to exhaust their administrative remedies here, because their challenge raises pure questions of law that cannot be decided through the administrative process. Plaintiffs argue that the Secretary lacked statutory authority to set the 2019 340B reimbursement rate at ASP minus 22.5%. *See* Pls.' Mot. Inj. at 2. The Court does not need a factual record to decide that question. And no administrative body has authority to rule in Plaintiffs' favor, even if Plaintiffs are correct on the law. *See* 42 C.F.R. § 405.1063(a) (stating that "[a]ll laws and regulations pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council"); HHS Expedited Access to Judicial Review Ruling at 6, ECF No. 19-1 (stating that "neither the ALJ nor the [Medicare Appeals]

Council has the authority to find the 2018 OPPS Rule invalid"). Plus, it is unlikely that further administrative appeals would cause the Secretary to rethink his position that he has authority to "adjust" 340B rates from ASP plus 6% to ASP minus 22.5%, based on the drugs' estimated acquisition costs. *See Tataranowicz*, 959 F.2d at 275. Even after this Court held the 2018 OPPS Rule unlawful, the Secretary left the identical 2019 OPPS Rule in place. Thus, because Plaintiffs have presented claims for reimbursement to the Secretary under the 2019 OPPS Rule, and because Plaintiffs' exhaustion of their administrative remedies would be futile, the Court waives Plaintiffs' exhaustion requirement and exercises its subject matter jurisdiction under 42 U.S.C. § 405(g).

Second, on the merits, the Secretary acted *ultra vires* in setting the 2019 340B reimbursement rate. *Ultra vires* review "is 'quite narrow.'" *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)). To successfully mount an *ultra vires* challenge, a plaintiff "must show a 'patent violation of agency authority.'" *AHA*, 348 F. Supp. 3d at 79 (quoting *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 522 (D.C. Cir. 2016)). "A violation is 'patent' if it is '[o]bvious' or 'apparent.'" *Fla. Health Scis. Ctr*, 830 F.3d at 522 (quoting Black's Law Dictionary (10th ed. 2014)). The Secretary's violation here is apparent.

The Secretary set the 2019 340B rate using his authority under 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(II) ("subsection II"). *See* 83 Fed. Reg. at 58,981 (incorporating the 2018 OPPS Rule's discussion of the Secretary's authority to reimburse 340B drugs at ASP minus 22.5%). Under that provision, a given drug's reimbursement rate "shall be equal . . . [to] the *average [sales] price for the drug* in the year established under . . . section 1395w-3a of this title

. . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." *Id.* (emphasis added). This Court previously held, based on the D.C. Circuit's decision in *Amgen*, that subsection II's plain text limits the Secretary's authority to adjust rates.[11] *See AHA*, 348 F. Supp. 3d at 79–81. Adopting the Circuit's reasoning, the Court concluded that "because the term adjustments" does not "encompass the power to make basic and fundamental changes in the [statutory] scheme . . . a more substantial departure from the default amounts would, at some point . . . cease to be an adjustment[]." *Id.* at 80 (internal quotation marks omitted) (quoting *Amgen*, 357 F.3d at 117). Put simply, because subsection II "only authorizes adjustments," it cannot not be read to permit the "total elimination or severe restructuring of the statutory scheme." *Id.* (quoting *Amgen*, 357 F.3d at 117). To do so would be *ultra vires*.

In "adjusting" the 2019 340B rate under subsection II, the Secretary made basic and fundamental changes to the statutory scheme. The rate covers reimbursement for potentially thousands of pharmaceutical products. *See* 82 Fed. Reg. at 52,494 (discussing the number of 340B "covered products" available to 340B Program participants). The Secretary expressly based that rate on the products' estimated acquisition costs. *See* 82 Fed. Reg. at 52,496, 52,500. That methodology—setting a drug's rate based on its acquisition cost—is contained in a

[11] In *Amgen*, the Circuit considered the Secretary's authority to adjust reimbursement rates under a different, but related, Medicare provision: 42 U.S.C. § 1395*l*(t)(2)(E). *See Amgen*, 357 F.3d at 107. Like subsection (t)(14)(A)(iii)(II), subsection (t)(2)(E) authorizes the Secretary to make "adjustments" to certain hospital reimbursement rates "as determined to be necessary to ensure equitable payments" under the OPPS scheme. 42 U.S.C. § 1395*l*(t)(2)(E). In addressing the *Amgen* plaintiff's claim that the Secretary exceeded his adjustment authority under subsection (t)(2)(E), the Circuit observed that "[l]imitations on the Secretary's equitable adjustment authority inhere in the text of § (t)(2)(E)." *Amgen*, 357 F.3d at 117. Thus, though the slight adjustment at issue in *Amgen* was not *ultra vires*, the Circuit left open the possibility that an adjustment of much greater magnitude could, in fact, "cease to be an 'adjustment[]'" at all. *Id.* (alteration in original) (quoting *MCI Telecomms. Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 225 (1994)).

Medicare subsection on which the Secretary could not rely, because he did not gather the necessary data—he did not have the "hospital acquisition cost survey data under subparagraph (D)." 42 U.S.C. § 1395*l*(t)(14)(A)(iii)(I) ("subsection I"). The subsection on which the Secretary did rely sets a drug's rate based on its average sales price, rather than its acquisition cost. *See id.* § (t)(14)(A)(iii)(II) ("subsection II").[12] The Secretary thus "adjusted" the 2019 340B rate using a methodology entirely decoupled from that established by the Medicare subsection on which he relied. Not to mention, the rate adjustment is not modest; it is a nearly 30% reduction from the default statutory formula. "When viewed together, the rate reduction's magnitude and its wide applicability inexorably lead to the conclusion that the Secretary fundamentally altered the statutory scheme established by Congress for determining SCOD reimbursement rates, thereby exceeding the Secretary's authority to 'adjust[]' SCOD rates under § (t)(14)(A)(iii)(II)."[13] *AHA*, 348 F. Supp. 3d at 81 (alteration in original).

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[12] Again, subsection II allows the secretary to set each 340B drug's reimbursement rate equal to "the average price for the drug in the year established under . . . section 1395w-3a . . . as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." 42 U.S.C. § (t)(14)(A)(iii)(II).

[13] The Secretary argues that his "adjustment" of the 2019 340B reimbursement rate is shielded by 42 U.S.C. § 1395*l*(t)(12). That provision precludes judicial review of certain types of Medicare rate adjustments. *See, e.g.*, 42 U.S.C. § 1395*l*(t)(12)(C) (barring judicial review of "periodic adjustments made under paragraph [(t)(9)]"). However, "the preclusion on review of" those adjustments "extends no further than the Secretary's statutory authority to make them." *Amgen*, 357 F.3d at 112. In other words, if the Secretary makes an "adjustment" within that term's meaning, subsection (t)(12) bars a court from reviewing the reasons underlying that adjustment. But if the Secretary's action is so extreme that it ceases to be an "adjustment," a court may review and strike down that action. *See id.* at 112–14; *AHA*, 348 F. Supp. 3d at 78–79; *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 20–21 (D.D.C. 2014). Here, because the Secretary exceeded his statutory authority to make an "adjustment" under subsection (t)(14)(A)(iii)(II), subsection (t)(12) does not preclude the Court from reviewing that action. *Cf. H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11–12 (D.D.C. 2018) (holding that the court would have jurisdiction, "under *ultra vires* review," to hear the plaintiff's claim that the agency was statutorily required to make an adjustment under subsection (t)(2)(E)). The Court thus need not determine whether subsection (t)(12) would preclude review of a lawful adjustment made under subsection (t)(14).

IV. REMEDIES

Having concluded that both the 2018 and 2019 340B reimbursement rates were unlawful, the Court must determine how to "unscramble the egg," so to speak. Determining the proper remedy is no easy task, given Medicare's complexity. The parties, unsurprisingly, take wildly divergent positions on this issue. Plaintiffs seek injunctive relief. *See* Pls.' Suppl. Remedies Br. ("Pls.' Remedy Br.") at 10–11, ECF No. 32. They ask this Court to (1) order the Secretary to pay Plaintiffs "the difference between the amount they received [under the 2018 and 2019 OPPS Rules] and the amount to which they are entitled (based on the ASP plus 6% methodology)"; and (2) order that Plaintiffs that have not yet received reimbursement for 340B drugs prescribed in 2018 and 2019 be paid "the amount they would have received under the 2017 OPPS rule."[14] *Id.* Defendants, on the other hand, ask this Court to remand the 2018 and 2019 OPPS Rules to HHS, without vacating the rules or imposing specific duties on the agency. *See* Defs.' Remedy Br. at 1–2, ECF No. 31.

The Secretary also argues that his adjustment is "committed to agency discretion by law," and is thus unreviewable under the APA. 5 U.S.C. § 701(a)(2). That argument fails for the same reason that the Secretary's statutory preclusion argument fails. A matter is committed to agency discretion when "the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The D.C. Circuit indicated in *Amgen*, however, that the statute at issue here *does* impose a meaningful standard: The Secretary may not use his adjustment authority to make fundamental changes to the statutory scheme. *See Amgen*, 357 F.3d at 117. "[A] court may not inquire into the 'necessity' of an 'adjustment' made by the Secretary, but that does not prevent the Court from inquiring into whether the Secretary's actions were, in fact, an 'adjustment' or something more." *AHA*, 348 F. Supp. 3d at 83 n.20.

[14] Plaintiffs' remedies briefing does not specifically discuss the 2019 OPPS Rule. However, in their motion for a permanent injunction, Plaintiffs ask this Court to (1) require the Secretary to amend the 2019 rule and implement a 340B rate of ASP plus 6%, and (2) "implement the same retrospective remedy that [P]laintiffs have proposed for 2018." Pls.' Mot. Inj. at 3–4.

The parties' briefing raises two questions regarding the appropriate remedy. First, should the Court issue an injunction or remand the issue to the agency? Second, if remand is appropriate, should the Court vacate the 2018 and 2019 OPPS Rules? Having reviewed the parties' briefing and the relevant case law, the Court concludes that remand without vacatur is most appropriate.

A. Remand is Appropriate

Remand, rather than an injunction, is the better course of action here. As Defendants note, "[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." *N. Air Cargo v. USPS*, 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). 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 *Cty. 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)).

At least one other court in this jurisdiction has followed this course under similar circumstances. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 19. In *Moffitt Cancer Center*, the plaintiff challenged the Secretary's decision *not* to make an OPPS rate adjustment under 42

U.S.C. § 1395*l*(t)(2)(E), arguing that the adjustment was required by statute. *Id.* at 10–11. The plaintiff sought an order requiring HHS to (1) vacate and amend a particular rule, and (2) "adjust [the plaintiff's] payments . . . accordingly." *Id.* at 18–19. The court agreed with the plaintiff on the merits, holding that the statute unambiguously required the Secretary to raise the plaintiff's OPPS rates under subsection (t)(2)(E). *See id.* at 13–14. But the court declined to grant the specific relief sought. *See id.* at 19. Instead, it "simply remand[ed] to HHS so that it c[ould] consider and adopt an 'appropriate adjustment.'" *Id.* The Court will take the same approach here.

Plaintiffs' arguments for injunctive relief are unpersuasive, and the case law weighs against them. Plaintiffs note that there are multiple ways for HHS to remediate its underpayments, some more complicated than others. *See* Pls.' Remedy Br. at 2–4, 7–8. This discussion illustrates why remand is best: Injunctive relief is typically appropriate when "there is 'only one rational course' for the [a]gency to follow upon remand." *Berge v. United States*, 949 F. Supp. 2d 36, 43 (D.D.C. 2013) (quoting *Am. Fed'n of Gov't Emps., AFL-CIO v. Fed. Labor Relations Auth.*, 778 F.2d 850, 862 n.19 (D.C. Cir. 1985)). As the parties' briefing makes clear, HHS has multiple courses on remand, including Plaintiffs' proposed mechanism.[15] Plaintiffs also note "recent examples of cases in which HHS has paid hospitals to compensate for past underpayments." Pls.' Remedy Br. at 4–7. But in each of those cases, the agency reached its own decision on remand; the courts did not grant injunctive relief. *See Cape Cod Hosp. v.*

[15] For example, HHS indicates that it could potentially adjust reimbursement rates in future years to make up for its underpayments in 2018 and 2019. *See* Defs.' Remedy Br. at 11. Or, it also indicates that it could amend the 2018 and 2019 OPPS Rules, and issue retroactive payments accordingly. *See id.* And as discussed below, there is some question as to whether the agency's actions must be budget neutral. The path forward is not sufficiently clear cut that this Court should chart it in the first instance.

Sebelius, 630 F.3d 203, 216 (D.C. Cir. 2011); *Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 18–19; *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 267–71 (D.D.C. 2015). Finally, Plaintiffs express concern that the Secretary may use remand to "further delay resolution of this matter" or even deny relief altogether. Pls.' Resp. Br. Remedies ("Pls.' Resp.") at 1, ECF No. 37. But the Court will retain jurisdiction over this matter, and the Court may reconsider the remedy if the agency fails to fulfill its responsibilities in a prompt manner. In short, Plaintiffs have provided no sound reason or case law to support deviating from the normal course in this jurisdiction under these circumstances: remand.

B. Vacatur is not Warranted

While it is a close question, the Court concludes that it is best to remand the 2018 and 2019 OPPS Rules without vacating them. In deciding whether vacatur is warranted, the Court turns to the standard articulated by the D.C. Circuit in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Commission*, 988 F.2d 146, 150–51 (D.C. Cir. 1993).[16] Under this standard, the Court must weigh "the seriousness of the [agency] order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Id.* (quoting *Int'l Union, United Mine Workers of Am. v. Fed. Mine Safety & Health Admin.*, 920 F.2d 960, 967 (D.C. Cir. 1990)). "There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors." *Shands*, 139 F. Supp. 3d at 270 (listing cases). "[R]esolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Id.*

[16] Both parties agree that this standard is applicable. *See* Defs.' Remedy Br. at 5; Pls.' Resp. at 2.

Plaintiffs state that they "are not urging this Court to vacate the portions of the 2018 OPPS Rule that the Court held unlawful." Pls.' Resp. at 2.[17] Yet, Plaintiffs also argue that the *Allied-Signal* factors weigh in favor of vacatur. *See* Pls.' Remedy Br. at 7 n.6; Pls. Resp. at 2. And their supplemental complaint expressly seeks vacatur. *See* Suppl. Compl. at 24 (asking this Court to "strike the changes in the payment methodology for section 340B drugs from the 2018 and 2019 OPPS Rules"). Regardless, the Court concludes that the *Allied-Signal* factors weigh, ever so slightly, against vacatur.

The Secretary's deficiencies here were substantial. He patently violated the Medicare Act's text. Unlike cases in which the agency's decision may have been lawful, but was inadequately explained, *see Am. Great Lakes Ports Ass'n v. Zukunft*, 301 F. Supp. 3d 99, 103 (D.D.C. 2018), no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner, *see Shands*, 139 F. Supp. 3d at 268 (holding that the first *Allied-Signal* factor weighed in favor of vacatur where the "flaw in the notice and comment process was substantial," and the court was not convinced that HHS would be able to justify its decision on remand). Rather, the Secretary would need to justify those rates under a different statutory provision—a nearly impossible task, given the Secretary's lack of relevant data. The Secretary argues that "there remains some 'doubt about whether the agency chose correctly,'" given that the D.C. Circuit could reverse this Court's decision on appeal. Defs.' Remedy Br. at 5 (quoting *Allied-Signal*, 988 F.2d at 150). That may be true. But the Secretary cites no case in which a court considered the losing party's potential success on appeal in determining the proper trial-

[17] This may be an eleventh-hour strategic decision. Perhaps Plaintiffs have decided that vacatur will increase the likelihood that HHS corrects its underpayments in a budget neutral manner, clawing back payments made to Plaintiffs for other Medicare-related services. *See* Pls.' Resp. at 10–11.

level remedy. Possible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility. The Court will not consider it here. The first *Allied-Signal* factor thus weighs in favor of vacatur.

On the other hand, vacatur would likely be highly disruptive. If the Court were to vacate the 2018 and 2019 OPPS Rules, it could order the Secretary to reinstate the rule previously in effect—the 2017 OPPS Rule—or leave it to the Secretary to issue new rules. *See Am. Great Lakes Ports*, 301 F. Supp. 3d at 103–04; *Oceana, Inc. v. Evans*, 389 F. Supp. 2d 4, 6 (D.D.C. 2005). Under either scenario, 340B reimbursement rates would presumably be higher than ASP minus 22.5%. While those higher rates would address Plaintiffs' harm, they would raise the following potentially serious administrative problems.

In general, OPPS payments must remain budget neutral, which could throttle the Secretary's ability to retroactively adjust reimbursement rates in the event of vacatur. *See, e.g.*, 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"); *id.* § 1395*l*(t)(14)(H) (stating that "[a]dditional expenditures resulting from" subsection (t)(14), after 2005, "shall be taken into account" in "establishing the conversion, weighting, and other adjustment factors" under subsection (t)(9)). Budget neutrality dictates that any increase in spending on certain aspects of Medicare Part B must be offset by decreases elsewhere in the program. *See Cape Cod*, 630 F.3d at 206 (noting that budget neutrality required the Secretary to implement a rate adjustment "in a manner that would have no effect on the annual total of Medicare payments made to all hospitals throughout the country for inpatient services").

The Secretary issued the 2018 and 2019 340B rates according to this principle: Because he decreased reimbursement rates for 340B drugs, he increased rates for other Medicare Part B products and services. *See* 82 Fed. Reg. at 52,623 (stating that HHS implemented the 340B "payment reduction in a budget neutral manner within OPPS," allowing HHS to "increase OPPS payment rates for non-drug items and services by approximately 3.2[%]"). Thus, if the Secretary were to retroactively raise the 2018 and 2019 340B rates, budget neutrality would require him to retroactively lower the 2018 and 2019 rates for other Medicare Part B products and services. And 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. *See* Decl. of Elizabeth Richter ¶¶ 5–9, ECF No. 31-1 (estimating that recoupment would take a year, require between $25 and $30 million in administrative costs, and adversely impact Medicare beneficiaries who would owe different amounts under their cost-sharing obligations).

The parties, and the Federation of American Hospitals,[18] strongly debate whether the Secretary's remedial rate adjustments must be budget neutral. *See* Pls.' Remedy Br. at 8–10; Defs.' Remedy Br. at 7–9; Amicus Br. at 4–7, ECF No. 38. Some courts in this jurisdiction have hypothesized, without concluding, that HHS's remedial adjustments need not be budget neutral. *See Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 15–16. The D.C. Circuit, on the other hand, has

[18] The Federation of American Hospitals filed an amicus brief on behalf of "more than 1,000" non-340B hospitals, addressing remedies. *See* Unopposed Mot. Leave File Amicus Curiae Br. at 1–2, ECF No. 33. The Federation also seeks leave to respond to the parties' briefing on this issue. *See* Mot. Leave File Amicus Curiae Br. at 1, ECF No. 40. Because the Court finds the Federation's briefing helpful, it exercises its "inherent authority" to allow the Federation's participation as amicus curiae. *Jin v. Ministry of State Sec.*, 557 F. Supp. 2d 131, 136 (D.D.C. 2008) (quoting *Smith v. Chrysler Fin. Co., LLC*, No. Civ.A. 00-6003, 2003 WL 328719, at *8 (D.N.J. Jan.15, 2003)). The Court will consider the Federation's response brief.

suggested the opposite, *see Amgen*, 357 F.3d at 112 (noting that "judicially mandated changes in one [OPPS] 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"), although it does not appear to have definitively weighed in. 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.[19]

Relatedly, the presumption against retroactive rulemaking would also complicate vacatur, given that vacatur would force the Secretary to retroactively issue rules for 2018 and 2019. *See* Pls.' Response at 10. 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." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). "Even where some substantial justification for retroactive rulemaking is presented, courts should be reluctant to find such authority absent an express statutory grant." *Id.* at 208–09.

Other courts grappling with this issue in the Medicare context have found that it weighs against vacatur. For instance, in *Shands*, another court in this jurisdiction considered whether to vacate an HHS rule reducing a particular reimbursement rate by 0.2% without adequate explanation. *See Shands*, 139 F. Supp. 3d at 263, 269. There, as here, it was "unclear whether the presumption against retroactive rulemaking would apply" if HHS were required to issue a new rule upon vacatur. *Id.* at 269. The Court held that the presumption's applicability weighed

[19] Budget neutrality is likely to cause disruption regardless of whether the Court vacates the 2018 and 2019 OPPS Rules. But remand without vacatur will 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.

against vacatur, because it would impact the agency's ability to navigate the proper remedial action. *See id.*; *cf. Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 198 (D.C. Cir. 2009) ("[W]e think it 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."); *Am. Great Lakes Ports*, 301 F. Supp. 3d at 104 (holding that vacatur was inappropriate where "it would appear that the Coast Guard would be unable to reinstate the 2016 rates through a properly justified new rule due to the presumption against retroactive rulemaking"). The same concern applies here: The Secretary may not be able to retroactively adjust 340B payments, at least not in a budget neutral manner, should the 2018 and 2019 OPPS Rules be vacated. Any attempt to do so would almost certainly trigger litigation. *See* Amicus Br. at 10 (asking this Court to determine that the Secretary "lacks authority to recoup any or all of the 3.2[%] budget neutrality adjustment" made in the 2018 OPPS Rule). Remand may allow the agency to avoid the issue altogether.[20]

It is true that, as Plaintiffs note, courts most commonly remand without vacatur agency decisions that suffer from procedural, rather than substantive, deficiencies. *See, e.g*, *Am. Great Lakes Ports*, 301 F. Supp. 3d at 104. But Plaintiffs cite no case law indicating that remand without vacatur is *never* appropriate for agency decisions suffering from severe deficiencies. Nor could they. *See North Carolina v. EPA*, 550 F.3d 1176, 1177–78 (D.C. Cir. 2008) (per curiam) (remanding an agency rule without vacatur, despite "more than several fatal flaws in the

[20] For instance, the Secretary may be able to raise 340B rates in future years to compensate for the 2018 and 2019 underpayments. *See Shands Jacksonville Med. Ctr., Inc. v. Azar*, No. 14-cv-263 *et al.*, 2018 WL 6831167, at *16 (D.D.C. Dec. 28, 2018) (affirming the Secretary's decision to implement a one-time, prospective rate increase to address underpayments in previous years). The Federation of American Hospitals contends that the Medicare Act does not authorize this type of prospective remedial adjustment in a budget neutral manner. *See* Amicus Br. at 9–10. But the Court need not decide that at this stage.

rule" (quoting *North Carolina v. EPA*, 531 F.3d 896, 901 (D.C. Cir. 2008) (per curiam))); *Shands*, 139 F. Supp. 3d at 270 (remanding the Secretary's rate reduction without vacatur, despite the action's serious deficiencies); *cf. Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991) ("[W]hen equity demands, an unlawfully promulgated regulation can be left in place while the agency provides the proper procedural remedy."). Given the "complex prospective payment system" at issue here, *Amgen*, 357 F.3d at 112, the Court concludes that vacating the 2018 and 2019 OPPS Rules would do more harm than good, despite the fatal flaws in the Secretary's 340B rate adjustments.

V. CONCLUSION

For the foregoing reasons, the Court concludes that the 340B drug reimbursement rate contained in the 2019 OPPS Rule is unlawful, because it was implemented in contravention of the Medicare Act's plain text. That said, the Court declines to grant the injunctive relief requested by Plaintiffs. Instead, the Court remands the 2018 and 2019 OPPS Rules to the Secretary without vacatur. Thus, Plaintiffs' Motion for a Permanent Injunction (ECF No. 35) is **GRANTED IN PART**, and Defendants' Motion to Dismiss (ECF No. 42) is **DENIED**. On or before **August 5, 2019**, the parties shall submit a status report regarding the agency's progress on remand to remedy the issues raised in this litigation concerning the 2018 and 2019 OPPS Rules. The Court expects that the agency will act expeditiously to resolve these issues. An order consistent with this Memorandum Opinion is separately and contemporaneously issued.

Dated: May 6, 2019

RUDOLPH CONTRERAS
United States District Judge