IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, *et al.*, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services, Defendant.	Case No. 1:18-CV-2841-RMC

REPLY IN SUPPORT OF MOTION TO MODIFY ORDER

Defendants have asked the Court to modify its order vacating a portion of the 2019 Outpatient Prospective Payment System (OPPS) Rule or, in the alternative, to stay its order to afford the Solicitor General time to determine whether to authorize appeal. Mtn. to Modify Order (Mtn. to Modify), ECF No. 33. Defendants offered a number of arguments in favor of the relief sought, but the most critical point is this: Vacating the challenged provisions of the OPPS rule will result in a regulatory vacuum. Plaintiffs predictably disagree. But their arguments are unconvincing. Stripped to their core, they constitute a request that the Court order the Agency to pay them at their preferred rate. The Court already correctly rejected this sort of request, however: "Plaintiffs not only ask for vacatur of the Final Rule, but also for a court order requiring CMS to issue payments improperly withheld due to the Final Rule. Plaintiffs' request will be denied." Memo. Op., ECF No. 31, at 26. It should do so again. Remand without vacatur is warranted.

Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n, 988 F.2d 146 (D.C. Cir. 1993), establishes a two-part test for determining whether to vacate a rule that has been declared unlawful: "The decision whether to vacate depends on the seriousness of the 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.* at 150-51. Application of the test requires the Court to exercise its discretion, as "[t]here is no rule requiring either the proponent or opponent of vacatur to prevail on both factors . . . Rather, resolution of the question turns on the Court's assessment of the overall equities and practicality of the alternatives." *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F Supp. 3d 240, 270 (D.D.C. 2015).

"[T]he overall equities and practicality of the alternatives" weigh in favor of remand without vacatur. First, there remains doubt about whether the Agency chose correctly. Mtn. to Modify at 4-5. Second, and more critically, vacatur will have disruptive consequences because, as Defendants explained in their opening brief, no methodology exists under which the Secretary may pay off-campus provider-based departments for the clinic visits that the challenged portion of the Rule addressed. *Id.* at 5. Relatedly, there is no methodology available for affected off-campus provider-based departments to calculate appropriate patient co-payments. *Id.* In its Order, the Court recognized that there can be "complications resulting from an order to vacate." Memo. Op. at 27. This is just one of those complications—and it is avoidable. The Court can amend its order to remand without vacatur. Remand without vacatur, moreover, will not prejudice plaintiffs, who—if they ultimately prevail—will be entitled to any difference in payment rates they are owed or to challenge the agency's administrative remedy if they remain unsatisfied.

Both sets of Plaintiffs respond essentially that the portion of the OPPS rule struck by the Court was an exception to the standard payment rule, and the Agency can be instructed to pay claims at that standard rate. AHA Plaintiffs' Opp., ECF No. 34, at 4-5; Univ. of Kansas Plaintiffs' Opp., ECF No. 35, at 6-8, 6 n.2 ("This Court's vacatur order entitles each of the Plaintiff Hospitals, by virtue of their status as named plaintiffs in *University of Kansas Hospital Authority v. Azar*, to payment at the full OPPS rate for each of their claims for E/M services that they furnished from January 1, 2019, going forward."). But this is not an argument that vacatur is not disruptive. It is an argument that any disruption could be remedied by an order requiring the Agency to pay Plaintiffs at their preferred rate.

Put otherwise, Plaintiffs' argument seems to be something along the lines of the following: "There was an exception; the exception is gone; now the standard OPPS rate for clinic visits applies." But the standard rate does not encompass these providers, as they were carved out. And the Court's determination that there was a flaw in the rate that was applied to the carved-out providers does not automatically trigger a broadening of the scope of applicability of the standard rate; the providers addressed by the exception are still carved out (but now exist in a regulatory vacuum). Application of the standard rate to plaintiffs, then, is not a *fait accompli*; it would require the Court to take a blue pencil to the OPPS rule to revise its terms. But as the Court properly recognized, Memo. Op. at 26, and as discussed more fully below, under the APA, it is not the Court's role to make such remedial choices. They are left to the agency in the first instance

D.C. Circuit precedent makes this point clear. For example, in *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013), the plaintiffs challenged a reverse-mortgage regulation issued by the U.S. Department of Housing and Urban Development (HUD). After laying out a series of

administrative steps that HUD could take on remand, the D.C. Circuit emphasized: "We do not hold, of course, that HUD is required to take this precise series of steps, nor do we suggest that the district court should issue an injunction to that effect. Appellants brought a complaint under the Administrative Procedure Act to set aside an unlawful agency action, and in such circumstances, it is the prerogative of the agency to decide in the first instance how best to provide relief." *Id.*

Northern Air Cargo v. U.S. Postal Serv., 674 F.3d 852, 861 (D.C. Cir. 2012), similarly demonstrates this agency-deference principle. Plaintiffs in that case challenged actions of the U.S. Postal Service. *Id.* at 860. The district court entered an injunction against the Postal Service. It should not have, the D.C. Circuit explained: "It was quite anomalous to issue an injunction. When a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal." *Id.* at 861. *See also Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) ("Thus, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards. Accordingly, the district court had jurisdiction only to vacate the Secretary's decision rejecting the hospital's revised wage data and to remand for further action consistent with its opinion. It did not, as the hospital contends, have jurisdiction to order either reclassification based upon those adjusted wage data or an adjusted reimbursement payment that would reflect such a reclassification.") (quotation marks and citation omitted from parenthetical).

Plaintiffs suggest that an exception to this normal no-injunction rule applies, because the agency can take but one action in response to the Court's order. AHA Plaintiffs' Opp., ECF No. 34, at 5; Univ. of Kansas Plaintiffs' Opp., ECF No. 35, at 14-17. This suggestion is flawed, both as to claims already paid and those not yet paid. For claims already paid under the regulatory provision the Court found unlawful, the Agency could retroactively pay each claim at the rate Plaintiffs identify, or it could prospectively increase payments for future visits as a proxy for retroactive payment. *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2018 WL 6831167, at *13 (D.D.C. Dec. 28, 2018) (approving prospective remedy). Or it could possibly do something else. Plaintiffs argue that the "something else" is limited by the Agency's ability to regulate retroactively. But there is no flat prohibition on the Secretary taking retroactive action. 42 U.S.C. § 1395hh(e)(1)(A) (permitting retroactive application of a substantive regulation when "(i) such retroactive application is necessary to comply with statutory requirements; or (ii) failure to apply the change retroactively would be contrary to the public interest"). And Plaintiffs cannot ask the Court to prospectively rule out any potential action with retroactive effects because, under the APA, only final agency actions—not potential ones—are subject to challenge. 5 U.S.C. § 704; *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 42 (D.D.C. 2008) (explaining that, under the APA, the Court lacks the authority, at the remedial stage of a case, to reject potential, non-final agency action). Similarly, as to services not yet paid, the Agency retains discretion to craft a remedy. Thus, the standard no-injunction rule applies.

It is particularly important for the Court to follow that rule—and abstain from issuing an "anomalous" injunction—in the context of Medicare reimbursement, because of the "substantial deference that Courts owe to the Secretary [of Health and Human Services] in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr., Inc. v.*

Azar, 2018 WL 6831167, at *13 (D.D.C. Dec. 28, 2018) (quoting *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)). And to avoid creating disruptive consequences that the Court cannot remedy, it should remand the matter without vacatur, to allow the Agency to determine what appropriate steps to take in conformance with the Court's order.

Another court in this district followed just this approach in a case involving one of the lead plaintiffs in this case. In *American Hospital Ass'n v. Azar*, 385 F. Supp. 3d 1 (D.D.C. 2019), Judge Contreras concluded that an aspect of the OPPS rule relating to the payment rate for certain drug purchases violated the Medicare statute.[1] *Id.* at 9-10. But after thorough briefing, Judge Contreras decided to remand without vacatur. He did so even though, in his view, the rule "suffer[ed] from . . . substantive" rather than procedural deficiencies. *Id.* at 15. In his estimation, the "highly disruptive" consequences of vacatur were too great. *Id.* at 13-15. And while the rule at issue in that case was enacted in a budget neutral fashion, budget neutral rules do not have a monopoly on disruptive consequences: A regulatory vacuum in the context of an ongoing payment system affecting nearly a million claims per month will also cause great disruption. Moreover, Judge Contreras recognized that vacatur could raise questions about the Agency's retroactive rulemaking authority, which too could cause unnecessary disruption—including through litigation. Those questions may arise anyway, but "[r]emand may allow the agency to avoid the issue altogether," if it adopts a prospective remedy. *Id.* at 15. Finally, Judge Contreras also rejected Plaintiff's requests for a remedial injunction. *Id.* at 11-12. In this case, the Court should follow the same well-reasoned path as Judge Contreras by remanding without vacatur and without issuing a remedial injunction.

[1] That decision is on appeal.

For the reasons stated above, the Court should remand without vacatur and without issuing a remedial injunction. In the alternative, the Court should stay its order to afford the Solicitor General time to determine whether an appeal is warranted.

Dated: October 7, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG
Senior Trial Counsel
BRADLEY P. HUMPHREYS
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, N.W.
Washington, D.C. 20005
Tel.: (202) 514-5838
Fax: (202) 616-8202
Bradley.Humphreys@usdoj.gov
Justin.Sandberg@usdoj.gov

Counsel for Defendant