IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER, and YORK HOSPITAL, *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *Defendant*.	Civil Action No. 1:18-cv-2841

PLAINTIFFS' OPPOSITION TO
DEFENDANT'S MOTION TO MODIFY ORDER

On September 17, this Court found the challenged portion of CMS's 2019 OPPS Final Rule at issue in this case to be *ultra vires.* Dkt. 31. The Court vacated Section X.B of the Secretary's Method to Control for Unnecessary Increases in the Volume of Outpatient Services, 83 Fed. Reg. 58,818, 59,004–015 (Nov. 21, 2018), and remanded to the agency for further proceedings consistent with its decision. Dkt. 32.

Defendant now makes a remarkable request: that the Court reconsider its vacatur decision "because there remains considerable doubt over the correct legal outcome" and "because vacatur would cause serious disruptive consequences to the OPPS payment system." Dkt. 33 at 2. In essence, Defendant seeks permission to continue to enforce the very portions of the Final Rule that this Court has already declared *ultra vires*, on the ground that Defendant

harbors "considerable doubt" that this Court was "correct." Alternatively, Defendant asks this Court to grant a 60-day stay so that the Government can consider whether to file an appeal and seek a stay pending appeal, all without addressing (let alone satisfying) the rigorous standards for a stay pending appeal. This Court should decline both invitations.

I. This Court Correctly Concluded That The Presumptive APA Remedy Of Vacatur Applies To Defendant's *Ultra Vires* Conduct.

Whether Defendant's request is viewed through the prism of Rule 59(e), which governs motions to "alter or amend" a judgment,[1] or Rule 54(b), which governs amendment of interlocutory orders, the result is the same: there is no basis for rescinding the vacatur.

The Court's decision to vacate the *ultra vires* portion of the Final Rule was a sound one, as Plaintiffs have previously argued, Dkt. 23 at 16–17, and this Court correctly held, Dkt. 31 at 26–27. "When a court concludes that agency action is unlawful, 'the practice of the court is ordinarily to vacate the rule.'" *Philbrick v. Azar*, No. CV 19-773 (JEB), __ F. Supp. 3d ___, 2019 WL 3414376, at *14 (D.D.C. July 29, 2019) (quoting *Ill. Pub. Telecomms. Ass'n v. FCC*, 123 F.3d 693, 693 (D.C. Cir. 1997)). A court retains discretion to remand violative agency conduct without vacatur, but only after taking into account (1) the "seriousness of the order's deficiencies" (and therefore the "extent of doubt whether the agency chose correctly") and (2) whether there would be substantial "disruptive consequences of an interim change that may itself be changed." *See Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150–151 (D.C. Cir. 1993). Nothing in the Government's arguments as to either factor warrants this

[1] Under Rule 59(e), the Defendant must show that there has been "an intervening change of controlling law, the availability of new evidence, or the need to correct a clear error or prevent manifest injustice." *See Fox Television Stations, Inc. v. FilmOn X, LLC*, 968 F. Supp. 2d 134, 140 (D.D.C. 2013) (quoting *Fox v. Am. Airlines Inc.*, 389 F.3d 1291, 1296 (D.C. Cir. 2004)).

Court's reconsideration. Nor have any of the factual or legal underpinnings of this Court's order changed in the last few weeks. Vacatur remains the proper remedy.

a. The vacated portion of the OPPS Final Rule is irreparably deficient.

First, the Government argues that there remains some "doubt about whether the agency chose correctly," and that "the potential for appellate review" weighs in favor of a remand without vacatur. Dkt. 33 at 4–5. The fact that the agency disagrees with an adverse decision does not constitute "doubt [that] the agency chose correctly"; that phrase is properly reserved for circumstances where the agency has failed to adequately *explain* its choice, not where the agency acted incurably *ultra vires*. The question asked in *Allied-Signal* is whether the agency's conduct under review is fatally flawed or can be fixed on remand. And the *ultra vires* nature of CMS's conduct makes vacatur the only reasonable remedy here. This is not a case where the agency could conceivably "be able to substantiate its decision on remand." *Allied-Signal*, 988 F.2d at 151. Unlike agency conduct held unlawful for lacking adequate explanation or because the agency failed to include factual support in the record, no amount of deliberation by CMS on remand can generate agency authority that Congress did not see fit to delegate. *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d 1, 12–13 (D.D.C. 2019) ("Unlike cases in which the agency's decision may have been lawful, but was inadequately explained, no amount of reasoning on remand will allow the Secretary to re-implement the 340B rates in the same manner."). *See also Humane Soc'y of the United States v. Jewell*, 76 F. Supp. 3d 69, 137 (D.D.C. 2014) ("the Court is certain that the agency cannot arrive at the same conclusions reached in the Final Rule because the actions taken were not statutorily authorized"), *aff'd sub nom. Humane Soc'y of United States v. Zinke*, 865 F.3d 585 (D.C. Cir. 2017).

As for "the potential for appellate review," that always-available argument should be rejected out of hand. To do otherwise would render the first *Allied-Signal* factor a dead letter, as "[p]ossible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility." *Am. Hosp. Ass'n v. Azar*, 385 F. Supp. 3d at 13.

There is nothing that CMS could do on remand to lawfully salvage the portion of the Final Rule that was vacated, and the Government does not argue otherwise. That all but ends the inquiry. Because the challenged CMS actions "were not statutorily authorized," the first *Allied-Signal* factor "strongly favors vacatur." *Humane Soc'y of the United States*, 76 F. Supp. 3d at 137.

b. Vacating the challenged portion of the Final Rule does not threaten substantial disruption.

The second *Allied-Signal* factor also favors vacatur. That factor turns on the likelihood of substantial disruption from a potentially interim change in the status quo. The Government's argument rests on the assumption that a "regulatory vacuum" would arise were the challenged portion of CMS's Final Rule vacated, purportedly because there would be "no extant methodology under which the Secretary may pay off-campus provider-based departments for the evaluation and management services that the challenged portion of the Rule addressed." Dkt. 33 at 5. That critical assumption is false.

The vacated portion of the Final Rule created a special *exception to the prevailing hospital payment rates* for excepted off-campus provider-based departments (PBDs). The Final Rule directs that the payment rate for clinic visit services billed by *excepted* off-campus PBDs be equal to the payment rate associated with those same clinic visit services billed by *non-excepted* off-campus PBDs. CMS accomplished this by applying the lower Physician Fee Schedule (PFS) rate, rather than the higher hospital rate, to clinic visit claims billed with the modifier for

excepted off-campus PBD services. *See* 83 Fed. Reg. at 59,009 (describing how payments were adjusted under the Final Rule). That payment reduction has now been declared unlawful. Removal of the offending rate reduction simply means that the prevailing hospital payment rates continue to apply to clinic visits at excepted off-campus PBDs (just as Congress intended). As this Court has recognized, because this exception was implemented in a non-budget neutral manner, it is very simple for the agency to restore the outpatient hospital payment rates in place of the PFS-equivalent payment rates without affecting other payment rates. In practical terms, CMS simply will stop applying the special rule for 2019 that reduced payment on clinic visit services billed with the modifier for excepted off-campus PBDs. Instead, CMS will pay for those claims using the default, published rate for clinic visits, just as it does for other services furnished by excepted, off-campus PBDs. As a result, CMS does not need to issue a new rule to replace the invalid one. The agency's lawful path forward following vacatur is both clear and easily traversed.

The Government responds with a sort-of severability argument, suggesting that if it knew the payment reduction would be vacated, CMS might have instead "reduced rates overall," or "used some other statutory avenue to reduce payment rates—either specifically with respect to clinic visits or for OPPS services as a whole—in order to address the increased volume of unnecessary services described in the Rule." Dkt. 33 at 6. That severability argument is a nonstarter. The fact that CMS might have chosen to pursue some other reduction to the OPPS payment rates instead of the action challenged in this lawsuit does not justify withholding relief on the portion of the Final Rule that has been declared *ultra vires*. This is especially true because the challenged payment cuts were never intended by the Government to be budget

neutral. As such, vacatur of the challenged cut is not required to be offset by some other cut elsewhere in the budget.

The Final Rule issued in November 2018 and became effective in January 2019, as necessitated by Medicare and APA rulemaking procedural requirements and the Congressional Review Act. Even assuming that CMS wanted to tweak payment rates for Calendar Year 2019 (whether for the same or other services) in order to accomplish another equivalent budget cut, the Government has no authority to make such changes retroactively. Permitting an open-ended remand for this purpose—effectively a system-wide mulligan for all of 2019—would wreak far more havoc than a straightforward vacatur of the Final Rule's *ultra vires* features, and would itself be legally defective.

Moreover, because CMS must continue to make payments for clinic visits at excepted off-campus PBDs on an on-going basis, declining to vacate the *ultra vires* portion of the 2019 Final Rule now—for payments being made by CMS this week, and next week, and throughout the end of the year—would cause far greater disruption down the road. Because "the potentially disruptive effects of vacatur" do not "occur in a vacuum," this Court must consider "the potentially disruptive effects that could flow from remand without vacatur." *See Friends of the Capital Crescent Trail v. Fed. Transit Admin.*, 218 F. Supp. 3d 53, 60 (D.D.C. 2016) (declining to reconsider vacatur order on motion for reconsideration).

For all of these reasons, the Court got it right the first time. The *ultra vires* portion of the Final Rule warrants vacatur.

II. No Stay Is Warranted In The Alternative.

Defendant's motion alternatively requests this Court to stay its order for sixty days. The Government suggests this stay is necessary "to afford the Solicitor General sufficient time to

decide whether to authorize appeal," and notes that it then may ask for yet *another* stay pending conclusion of the appeal. Dkt. 33 at 7 & n.3.

That is an extraordinary request. First, the Government does not even indicate that an appeal is likely, let alone certain. And second, the Government fails to address any of the traditional stay factors, let alone present a compelling argument for a stay. *See Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977). The Government does not argue—let alone demonstrate—irreparable harm, or a likelihood of success, or public interest, or balancing of harms. There simply is no basis to grant a stay of the Court's Order on the record before the Court.

Worse, the Government appears to be running out the clock. The 2019 OPPS Final Rule is in effect for ninety more days, until December 31, 2019. CMS should be forced to come into compliance with the law, before the expiration of the Final Rule that is the subject of this lawsuit, and before the 2020 OPPS rule containing the same site neutral payment cuts is finalized and becomes effective.

III. Plaintiffs Request Further Briefing on Remedies.

The Government has not yet taken a position on the remedy issues that were flagged in the Court's Order, including how it will compensate hospitals that have been undercompensated since January 2019. Instead, it requests remand without vacatur so that CMS may unilaterally craft its own remedy in the first instance. *See* Dkt. 33 at 7 ("Perhaps the agency would choose to prospectively increase payment to exempt off-campus PBDs as a remedy for the previous payment decrease. Perhaps, instead, the agency would make payment changes retroactively. Perhaps there is another option.").

That would, of course, virtually ensure that this Court would not be able to address remedy until after expiration of the Final Rule under review.

Further delay is unwarranted. On remand, CMS could not avoid, at a bare minimum, prompt repayment of the contested amounts retroactively back to January 1, 2019 for all hospitals that were underpaid as a result of the *ultra vires* portion of the Final Rule. Anything short of that would countenance the agency's *ultra vires* conduct. To avoid needless delay, the Court should order CMS to provide that remedy promptly, without permitting the agency yet another opportunity for delay. The unique nature of CMS's overreach means that the "outcome of a new administrative proceeding is preordained" such that this Court may forgo "the futile gesture of remand." *Huff v. Vilsack*, 195 F. Supp. 3d 343, 362 (D.D.C. 2016) (quotations omitted).

Barring such an Order, Plaintiffs request the opportunity to submit briefing after learning of the Government's proposed remedy.

CONCLUSION

For the foregoing reasons, Defendant's Motion to Modify should be denied, and their alternative, unsupported Motion to Stay also denied.

Respectfully submitted,

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THE AMERICAN HOSPITAL ASSOCIATION, ASSOCIATION OF AMERICAN MEDICAL COLLEGES, MERCY HEALTH MUSKEGON, CLALLAM COUNTY PUBLIC HOSPITAL NO. 2 d/b/a/ OLYMPIC MEDICAL CENTER, and YORK HOSPITAL, *Plaintiffs,* v. ALEX M. AZAR II, in his official capacity as SECRETARY OF HEALTH AND HUMAN SERVICES, *Defendant*.	)	Civil Action No. 1:18-cv-2841

PROPOSED ORDER

Upon consideration of Defendant's Motion to Modify Order, the opposition(s) thereto, and the record herein, it is hereby

ORDERED, that Defendant's Motion BE, and it hereby IS, DENIED.

SO ORDERED, this ___ day of October, 2019.

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Rosemary M. Collyer
United States District Court Judge

Copies to:

Counsel of record through ECF