

that the Court stay the portion of its Order vacating the Rule for sixty days from the date of the Order to allow the Solicitor General time to determine whether to authorize appeal. If the Court intended for the vacatur to have immediate effect, there would be no payment rule in effect and no methodology by which Defendant could make payments for affected outpatient hospital claims.

Vacatur is not justified under the law of this Circuit, because there remains considerable doubt over the correct legal outcome and, more urgently, because vacatur would cause serious disruptive consequences to the OPSS payment system—particularly with respect to the services at issue in this litigation. Vacatur could also irreparably harm Defendant if it is required to pay Plaintiffs at a higher payment rate now and then ultimately prevails on any appeal, because Defendant has no administratively practical way to recoup the overpayments. On the other hand, modifying the Order to provide for remand without vacatur of the challenged portion of the 2019 OPSS Rule would allow for continued orderly payment to exempt off-campus PBDs, preserve Defendant’s appeal rights, and would not prejudice Plaintiffs, who—if they ultimately prevail—will be entitled to any difference in payment rates they are owed.

BACKGROUND

Plaintiffs brought this action to challenge a portion of Defendant’s most recent rule revising the OPSS payment system, *Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting*, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Rule). The Rule sets rates for all payments under the OPSS for the 2019 calendar year. In the specific portion of the Rule that Plaintiffs challenged, CMS sought to use its authority under Subsection (t)(2)(F) of the Medicare statute to pay for certain outpatient clinic visit services provided at excepted off-campus provider-based

departments (PBDs) at the same rate that CMS uses to pay non-excepted off-campus PBDs for those services under the separate Physician Fee Schedule. *See id.* at 59,004–15.

The parties filed cross motions for summary judgment, and briefing was complete on April 19, 2019. On September 17, 2019, the Court granted Plaintiffs' motion for summary judgment and denied Defendant's cross-motion. *See Order*, ECF No. 32. In that Order, the Court also vacated the challenged portion of the Rule and remanded this matter to the Secretary for further proceedings consistent with the Court's accompanying Memorandum Opinion. *See id.* at 1. The Court further ordered the parties to submit a joint status report no later than October 1, 2019, discussing whether additional briefing regarding remedies is necessary. *Id.* at 2. Given the Court's potential consideration of remedy briefing as contemplated by the Order, it is not entirely clear whether the Court intended its vacatur to have immediate effect.

ARGUMENT¹

Defendant respectfully submits that the Court should modify its Order to remand this matter to the agency without vacatur. Under Federal Rule of Civil Procedure 54(b), the Court has discretion to reconsider an interlocutory order. *Lewis v. District of Columbia*, 736 F. Supp. 2d 98, 102 (D.D.C. 2010). A court will grant a motion for reconsideration of an interlocutory order if a movant shows, among other things, a clear error in the first order. *Zeigler v. Potter*,

¹ Defendant recognizes that this Court contemplated further briefing regarding remedies only after the parties' submission of a joint status report on or before October 1, 2019. However, given uncertainty regarding whether the Court intended its vacatur to have immediate effect and the potential for serious disruption to OPSS payments if that is the case, among other reasons, as discussed below, Defendant asks the Court to consider modification of its September 17, 2019 Order on a more expedited basis. Moreover, out of an abundance of caution, Defendant respectfully asks that the Court stay the portion of the Order vacating the challenged portion of the Rule while the instant motion is under consideration, to avoid any possibility of noncompliance with the Court's order, even if the Court ultimately denies Defendant's requested relief.

555 F. Supp. 2d 126, 129 (D.D.C. 2008), *aff'd*, No. 09-5349, 2010 WL 1632965 (D.C. Cir. Apr. 1, 2010) (quotation marks omitted).

The D.C. Circuit set out the framework for evaluating whether to vacate a rule that the court has concluded violates the law in *Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146 (D.C. Cir. 1993). Application of that test here demonstrates that vacatur is not warranted. “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. “There 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).

Neither *Allied-Signal* factor favors vacatur. First, there remains some “doubt about whether the agency chose correctly,” *Allied-Signal*, 988 F.2d at 150, notwithstanding the Court’s decision that CMS exceeded its authority to control an unnecessary increase in the volume of certain excepted off-campus PBD services and therefore acted in an *ultra vires* fashion. Defendant acknowledges but respectfully disagrees with the Court’s conclusion that CMS’s use of its Subsection (t)(2)(F) authority was “inconsistent with the statutory scheme.” Memorandum Opinion at 19, ECF No. 31. As Defendant explained in its motion for summary judgment, CMS complied with Congress’s directive to develop a method to control unnecessary increases in the volume of OPD services paid through the OPPS. *See* Def.’s MSJ at 14-15 (citing 42 U.S.C. § 1395l(t)(2)(F)). Congress conspicuously excluded any requirement that CMS exercise that authority in a budget-neutral manner, and CMS may develop a method (which includes reducing

rates) to apply to individual OPD services that it determines are unnecessary. *See, e.g.*, Def.'s MSJ at 14-21. For all the reasons explained in Defendant's earlier briefs, there is "doubt about whether the agency chose correctly," and, given the potential for appellate review, some possibility that CMS would be permitted to make that choice again. *Allied-Signal*, 988 F.2d at 150.

More pressingly, given Defendant's continuing obligation to make payments while the state of the challenged portion of the Rule is unsettled, *see* 42 C.F.R. § 405.922, the second *Allied-Signal* factor weighs heavily against vacating the rule. If the challenged portion of the Rule remains vacated, CMS will be in an untenable position. Because the Court vacated the challenged portion of the Rule, there is currently 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. Similarly, given the regulatory vacuum created by the vacatur, there is no methodology available for affected off-campus provider-based departments to calculate appropriate patient co-payments.

Defendant expects Plaintiffs to argue that Plaintiffs should simply be paid at the payment rate that would be in place but for CMS's exercise of its Subsection (t)(2)(F) authority. Yet, the portion of the 2019 OPPS Rule addressing payment for clinic visits to Plaintiffs and other exempt off-campus PBDs cannot be severed from the rest of the OPPS rates set forth in the 2019 OPPS Rule. "Severance and affirmance of a portion of an administrative regulation is improper if there is 'substantial doubt' that the agency would have adopted the severed portion on its own." *Davis County Solid Waste Mgmt. & Energy Recovery Special Serv. Dist. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir. 1997). Here, there is substantial doubt the agency would have adopted the remainder of the 2019 OPPS Rule in the same form if not for the implementation of

a method to reduce the volume of the services provided by excepted off-campus PBDs at issue in this litigation. When setting the payment schedule for 2019 in the Rule, CMS took into account the approximately \$300 million reduced expenditure that would result from CMS's exercise of its Subsection (t)(2)(F) authority. Thus, the Court cannot assume that rates would have remained the same in the absence of the vacated portion of the Rule.² Alternatively, CMS may have reduced rates overall or used some other statutory avenue to reduce payment rates—either specifically with respect to clinic visits or for OPSS services as a whole—in order to address the increased volume of unnecessary services described in the Rule, *see* 83 Fed. Reg. at 59,005–06.

Remand without vacatur would be a far better option. It would allow Plaintiffs to continue to receive payment as contemplated by the Rule until CMS takes further regulatory action consistent with the Court's Memorandum Opinion and/or during the pendency of any appeal. On the other hand, if CMS were to pay Plaintiffs at the current 2019 OPSS rate governing clinic visits for campus-based PBDs, and if Defendant were to successfully appeal the Court's decision, those payments could result in an unjustified windfall to Plaintiffs, because, as a practical matter, it would be very difficult for CMS to claw back overpayments to providers made through the OPSS given the administrative difficulty of doing so. Similarly, higher payments to Plaintiffs during any appeal period would also necessarily mean higher co-payments by beneficiaries. *See, e.g.*, 42 C.F.R. § 419.40(b)(1), (2) Thus, if the challenged portion of the Rule remains vacated, and CMS were to ultimately prevail on appeal, it would likely mean that beneficiaries would be overcharged for services in the interim.

² Defendant also cannot use the rates that were in effect under the rule previously in effect, before the 2019 OPSS Rule, because that rule was promulgated to cover only a single calendar year, given the regulatory requirement for the agency to annually update the OPSS payment rates. 42 U.S.C. § 1395l(t)(9).

Remand without vacatur would also afford the agency an opportunity to craft a remedy in the first instance, which is consistent with 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)). Perhaps the agency would choose to prospectively increase payment to exempt off-campus PBDs as a remedy for the previous payment decrease. *See id.* at 12–13. Perhaps, instead, the agency would make payment changes retroactively. Perhaps there is another option. Whatever the case, the choice should rest with the agency in the first instance, given the potential for disruption in the immense and complex system that has been entrusted to the agency to operate.

Defendant has contacted counsel for Plaintiffs regarding this motion, who indicated that Plaintiffs oppose Defendant’s requested relief.

CONCLUSION

For the foregoing reasons, Defendant respectfully asks that the Court modify its September 17, 2019 Order to remand this matter to the agency for further proceedings without vacatur. If the Court denies this motion and vacates the challenged portion of the Rule, or orders any other remedies, then Defendant respectfully requests that the Court stay the order for a period of at least sixty days to afford the Solicitor General sufficient time to decide whether to authorize appeal. 28 C.F.R. § 0.20(b); 28 U.S.C. § 2107(b).³

Dated: September 23, 2019

Respectfully submitted,

JOSEPH H. HUNT
Assistant Attorney General

³ If an appeal is authorized, Defendant may seek a stay of this Court’s judgment pending resolution of the appeal.

MICHELLE R. BENNETT
Assistant Branch Director

/s/ Bradley P. Humphreys

BRADLEY P. HUMPHREYS

JUSTIN SANDBERG

Trial Attorneys, U.S. Department of Justice

Civil Division, Federal Programs Branch

1100 L Street, N.W.

Washington, D.C. 20005

Tel.: (202) 305-0878

Fax: (202) 616-8470

Bradley.Humphreys@usdoj.gov

Justin.Sandberg@usdoj.gov

Counsel for Defendant