UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

| AMERICAN HOSPITAL ASSOCIATION, et al., | |
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| Plaintiffs, | |
| v.) | Civil Action No. 18-2841 (RMC) |
| ALEX M. AZAR II, | |
| Secretary of the Department of Health) | |
| and Human Services, | |
| , and the second se | |
| Defendant. | |
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MEMORANDUM OPINION

Previously, the Court held that the Centers for Medicare & Medicaid Services (CMS) exceeded its statutory authority when it selectively reduced by Final Rule reimbursement rates under the Outpatient Prospective Payment System (OPPS) to off-campus provider-based departments for certain outpatient department (OPD) services. *See Am. Hosp. Ass'n v. Azar*, No. 18-2841, 2019 WL 4451984 (D.D.C. Sept. 17, 2019); 83 Fed. Reg. 58,818 (Nov. 21, 2018) (Final Rule). Specifically, the Court determined that the addition of a non-budget-neutral rate reduction for Evaluation and Management (E&M) services at such facilities—separate from the normal OPPS reimbursement schedule—conflicted with the overall statute. *Am. Hosp. Ass'n*, 2019 WL 4451984, at *8-12. Accordingly, the Court vacated the relevant portions of the Final Rule, left intact the rest of the OPPS reimbursement schedule, and remanded the matter back to the agency for proceedings consistent with its decision. *Id.* at *12. However, given the complexities of setting and administering Medicare payments rates, the Court also ordered the parties to submit a status report to determine if additional briefing was required. *Id.*

CMS now asks the Court to modify its Order and to instead remand the matter to the agency to develop a remedy in the first instance, without vacatur. Alternatively, CMS asks for a 60-day stay of the Order while it considers whether or not to appeal. Plaintiffs oppose.¹ For the reasons below, the Court will neither modify nor stay the Order.

I. ANALYSIS

A. Vacatur

The D.C. Circuit has "made clear that '[w]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated." *Nat'l Min.*Ass'n v. U.S. Army Corps of Eng'rs, 145 F.3d 1399, 1409 (D.C. Cir. 1998) (quoting Harmon v. Thornburgh, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). That said, a court has discretion to remand an unlawful rule without vacatur depending on (1) "the seriousness of the [rule]'s deficiencies (and thus the extent of doubt whether the agency chose correctly)" and (2) "the disruptive consequences of an interim change that may itself be changed." *Allied-Signal, Inc. v. U.S. Nuclear-Regulatory Comm'n*, 988 F.2d 146, 150-51 (D.C. Cir. 1993). Neither factor is dispositive. "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) (*Shands I*).

As to the first factor, CMS "respectfully disagrees" with the Court's decision and maintains that its rate cut was a permissible "method for controlling unnecessary increases in the volume of covered OPD services." *See* 42 U.S.C. § 1395*l*(t)(2)(F). CMS thus argues that there is a live question regarding "whether the agency chose correctly" that may be resolved on appeal.

¹ See 9/17/2019 Order [Dkt. 32]; Mot. to Modify Order (Mot.) [Dkt. 33]; Pls.' Opp'n to Def.'s Mot. to Modify Order [Dkt. 34]; Mem. of the Univ. of Kansas Hosp. Auth. Pls. in Opp'n to Mot. to Modify [Dkt. 35]; Reply in Supp. of Mot. to Modify Order (Reply) [Dkt. 37].

CMS devotes little space to this argument. This factor may weigh in the government's favor when a decision within the agency's discretion was potentially lawful but insufficiently explained. See Heartland Reg'l Ctr. v. Sebelius, 566 F.3d 193, 198 (D.C. Cir. 2009) ("When an agency may be able readily to cure a defect in its explanation of a decision, the first factor in Allied-Signal counsels remand without vacatur."); see, e.g., Allied Signal, 988 F.2d at 151 ("It is conceivable that the Commission may be able to explain how the principles supporting an exemption for education institutions do not justify a similar exemption for domestic UF₆ converters."); cf. Am. Hosp. Ass'n v. Azar, 385 F. Supp. 3d 1, 13 (D.D.C. 2019) (finding a CMS rule could not be justified because the necessary data did not exist). But here the Court determined that CMS put forth an impermissible interpretation of the statutory scheme; no amount of new data or reasoning on remand can save its interpretation. See Humane Soc'y of the U.S. v. Jewell, 76 F. Supp. 3d 69, 137 (D.D.C. 2014) ("[T]he 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."). Nor does its hope of reversal on appeal help because "[p]ossible success on appeal would weigh against vacatur in every case, given that reversal is always a possibility." Am. Hosp. Ass'n, 385 F. Supp. 3d at 13. The first factor clearly favors vacatur.

As to the second factor, CMS argues more forcefully that for several reasons the disruption caused by vacating the rule weighs heavily in favor of remand only. First, CMS contends that without the rule "there is currently no extant methodology under which the Secretary may pay off-campus provider-based departments for the . . . services that the challenged portion of the Rule addressed." Mot. at 5. CMS similarly contends that "there is no methodology available for affected off-campus provider-based departments to calculate appropriate patient co-payments." *Id*.

These contentions fail to convince. Because CMS believed that it had authority to implement the E&M rate reduction independent of its authority to review and adjust OPPS relative payment weights, it developed underlying OPPS reimbursement rates and then tacked the E&M rate reduction on at the end. *See* Final Rule at 59,014 (applying the reduced E&M rates to the "final payment rates" for OPPS). As Plaintiffs describe it, CMS created an exception to OPPS reimbursement rates for only E&M services and only at applicable off-campus provider-based departments; vacating the rate reduction for E&M services at off-campus provider-based departments merely reverted such off-campus provider-based departments to the general rule. Indeed, CMS admits that there are extant OPPS reimbursement rates for *on*-campus provider-based departments which the relevant off-campus provider-based departments would have been subject to but for the Final Rule.² *See* Mot. at 6.

Anticipating this, CMS argues that vacatur leaves behind no OPPS reimbursement rates because the rate reduction for E&M services "cannot be severed from the rest of the OPPS rates set forth in the [Final] Rule." *Id.* at 5. The D.C. Circuit has held that "[s]everance 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 Cty. Solid Waste Mgmt. v. EPA*, 108 F.3d 1454, 1459 (D.C. Cir 1997). CMS asserts that it accounted for its projected \$300 million in projected savings when developing the underlying OPPS

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² CMS argues that payments to off-campus provider-based departments for E&M services would not revert to the general rule because such services have been carved out and reduced. *See* Reply at 3. Only the challenged rate reduction carved E&M services out of the general rule; all other patient services at off-campus provider-based departments continue to be paid at OPPS rates. The rate reduction was vacated as beyond the authority of CMS; therefore, such selected services are no longer carved out and should be paid according to the general rule.

reimbursement rates, and that without the rate reduction for E&M services it might have utilized other statutory means to accomplish the same ends or cut reimbursement rates across the board.

There is not nearly enough evidence to find "substantial doubt' that the agency would have adopted the severed portion on its own." Id. To start, that the rate reduction for E&M services can be so easily severed from the Final Rule as a practical matter strongly suggests that severance is appropriate as a legal matter. See Am. Petroleum Inst. v. EPA, 862 F.3d 50, 72 (D.C. Cir. 2017) ("Thus we have severed provisions when 'they operate[d] entirely independently of one another.") (quoting Davis Cty., 108 F.3d at 1459). That is, unlike other cases, the underlying OPPS reimbursement rates here were not "expressly conditioned" on rate reduction for E&M services. North Carolina v. FERC, 730 F.2d 790, 796 (D.C. Cir. 1984). Further, this is not a case where the remaining rule starts to lose meaning without the severed portion. See MD/DC/DE Broadcasters Ass'n v. FCC, 253 F.3d 732, 740 (D.C. Cir. 2001) (examining "whether a statute's function would be impaired if, after invaliding a portion of an implementing regulation, the Court left the rest of the regulation in place"). Indeed, there is no evidence at all that CMS considered the underlying OPPS reimbursement scheme when it decided to reduce rates for E&M services at off-campus provider-based departments, other than to note that the OPPS reimbursement rates were higher than comparable rates at physician offices. Rather, the reduced rate for E&M services "operate[d] entirely independently" of the underlying OPPS reimbursement scheme and was "not in any way 'intertwined'" with CMS's obligation to review and set those underlying OPPS reimbursement rates. Davis Cty., 108 F.3d at 1459 (quoting Tel. & Data Sys., Inc. v. FCC, 19 F.3d 42, 50 (D.C. Cir. 1994)). In fact, that independence was CMS's explanation for why budget neutrality did not apply. See Def.'s Opp'n to Pls.' Mot. for Summ. J. & Mem. in Supp. of Mot. to Dismiss or, in the Alternative, CrossMot. for Summ. J. [Dkt. 20-1] at 14-15. Regardless of what CMS hypothetically might have done, nothing in the Final Rule implies that the E&M rate reduction and underlying OPPS reimbursement rates were intended to be inseparable.

The Court further notes that the only material difference between the Proposed Rule and the Final Rule is that CMS chose to implement the rate reduction for E&M services over two years instead of one. *Compare* 83 Fed. Reg. 37,046, 37,143 (July 31, 2018) (Proposed Rule), *with* Final Rule at 59,013-14. CMS thus projected it would save only \$300 million due to the Final Rule, or half of the \$600 million originally projected. *See* Final Rule at 59,014. Yet CMS did not change the underlying OPPS reimbursement rates in the Final Rule to account for the \$300 million shortfall caused by phased implementation. CMS does not explain why the \$300 million shortfall caused by vacatur should be treated differently. CMS's silence in the Final Rule indicates that it would have implemented the underlying OPPS reimbursement rates even without a rate reduction for E&M services and also favors vacatur. *Cf. North Carolina*, 730 F.2d at 796 (severing a regulation despite resulting "nominal effects").

Second, CMS argues that vacating the Final Rule would prove disruptive if CMS were to succeed on appeal because, as a practical matter, it would be difficult for CMS to claw back any overpayments due to the administrative costs of doing so. *See* Mot. at 6. However, if CMS were to lose on appeal, this disruption would not come to pass. That may seem obvious, but the point is that CMS's argument has nothing to do with the appropriateness of vacatur in this case, only its timing; CMS's argument better supports its request for a stay pending appeal and is addressed below.³

³ Although the D.C. Circuit has noted "the havoc that piecemeal review of OPPS payments could bring about," *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004), that havoc is born of the

Finally, CMS argues that the Court should grant CMS the opportunity to develop a remedy in the first instance, in recognition of the "substantial deference that Courts owe to the Secretary in the administration of such a 'complex statutory and regulatory regime.'" *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 366 F. Supp. 3d 32, 54 (D.D.C. 2018) (quoting *Good Samartian Hosp. v. Shalala*, 508 U.S. 402, 404 (1993)); *see also N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012). But in each of the cases cited by CMS, deference was not an independent reason to remand without vacatur. Rather, remand without vacatur was found appropriate only after application of the *Allied-Signal* factors. *See N. Air Cargo*, 674 F.3d at 860-61; *Am. Hosp. Ass'n*, 385 F. Supp. 3d at 12-15; *Shands I*, 139 F. Supp. at 269-70. For the reasons above, those factors do not favor CMS here.

B. Stay of the Order

District courts generally have the authority to stay their orders pending appeal. See Hilton v. Braunskill, 481 U.S. 770, 776 (1987); Fed. R. Civ. P. 62(c). But in determining whether to grant a stay, courts consider four factors: "(1) whether the stay applicant has made a strong showing that he is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies." Hilton, 481 U.S. at 776. At most, CMS has only hinted at irreparable harm. But cf. Tataranowicz v. Sullivan, No. 90-0935, 1991 WL 57005, at *1 (D.D.C. Feb. 26, 1991) (finding disbursement of

prospective and budget neutral elements of the statutory scheme, neither of which is implicated here. Vacating the select rate reduction does not directly affect the broader reimbursement scheme. *Cf. Am. Hosp. Ass'n*, 385 F. Supp. 3d at 12-15 (declining to vacate an *ultra vires* budget neutral rule).

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Medicare payments and administrative costs of recoupment are not irreparable harm). It has

completely ignored the other factors. Without more, CMS has not satisfied its burden.

II. **CONCLUSION**

The *ultra vires* consequences of the Final Rule are not so complex that they

cannot be directly redressed or undone. Vacatur and remand are the correct remedies and CMS

has not established that a stay is appropriate at this time. The government's Motion to Modify

Order, Dkt. 33, will be denied. The Court will enter final judgment. A memorializing Order

accompanies this Memorandum Opinion.

Date: October 21, 2019

ROSEMARY M. COLLYER

United States District Judge

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