IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

THE AMERICAN HOSPITAL ASSOCIATION, <i>et al.</i> ,)))
Plaintiffs,) Case No. 1:18-CV-02841-RMC
V.)
ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,)
Defendant.)
)
UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, <i>et al.</i> ,)))
Plaintiffs,) Case No. 1:19-CV-00132-RMC
v.))
ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services,)
Defendant.)
))

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION TO ENFORCE JUDGMENT

INTRODUCTION

As part of its yearly process to establish Medicare rates under the Outpatient Prospective Payment System (OPPS), the U.S. Department of Health and Human Services (HHS) recently published a new rule setting those rates for the 2020 calendar year. Because the new rule effectively reduces payment rates in the same manner as the 2019 rule that Plaintiffs challenged in this case, Plaintiffs ask the Court to enforce the Court's prior judgment, which addressed the 2019 OPPS rule, but now with respect to 2020 rule. The Court should deny Plaintiffs' request.

Defendant, of course, recognizes that this Court already concluded that HHS's method to control unnecessary increases in volume in the 2019 OPPS Rule was *ultra vires*. And, while the government may appeal the Court's decision, Defendant further recognizes that, if Plaintiffs in this case were to bring a proper challenge to the Subsection (t)(2)(F) method implemented in the 2020 OPPS Rule, the Court may well find it to be *ultra vires* for the same reasons. As such, Defendant would willing to work with Plaintiffs to expedite any new case challenging the 2020 rule if Plaintiffs were to bring one after the 2020 rule goes into effect and Plaintiffs properly present a claim to the agency. However, Plaintiffs' request that the Court enforce its judgment in this case (regarding the 2019 OPPS Rule) as to a different rule (the 2020 OPPS Rule) that has not yet gone into effect (and that Plaintiffs have not even challenged) is fatally flawed. As described below, Plaintiffs' motion ignores the nonwaivable presentment requirement embodied in the Medicare statute, and it misinterprets the proper scope of the Court's September 17, 2019 order. Defendant respectfully asks that the Court deny Plaintiffs' motion.

BACKGROUND

Each year, through notice-and-comment rulemaking, HHS establishes the rates that Medicare will pay hospitals for the upcoming year under the OPPS. In the rule that established

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rates for 2019, HHS developed and implemented a volume-control method pursuant to its authority under Subsection (t)(2)(F) to control unnecessary increases in the volume of certain clinic visit services. *See* 83 Fed. Reg. 58,818, 59,014 (Nov. 21, 2018) (2019 OPPS Rule); *see also* 42 C.F.R. § 1395*l*(t)(2)(F). Although HHS indicated that it intended to phase in its method for controlling unnecessary increases in the volume of clinic visit services over two years, *id.* at 59,914, the 2019 OPPS Rule set rates only for payments made in the 2019 calendar year, *id.* at 58,818 ("This final rule . . . revises the Medicare hospital outpatient prospective payment system . . . for CY 2019 to implement changes arising from our continuing experience with these systems.").

Plaintiffs brought this action to assert that HHS's use of its Subsection (t)(2)(F) authority in the 2019 OPPS Rule was *ultra vires*. Plaintiffs initially filed suit on December 4, 2018, *see* ECF No. 1. However, Plaintiffs filed an Amended Complaint on January 29, 2019—after the 2019 OPPS Rule had gone into effect—in order to add allegations that the Plaintiff-Hospitals "presented claims to their Medicare Administrative Contractors (MACs)" after the 2019 OPPS Rule went into effect on January 1, 2019. *See* Am. Compl. ¶ 15. The parties cross moved for summary judgment, and the Court granted Plaintiffs' motion on September 17, 2019. ECF No. 31. The Court agreed with Plaintiffs that HHS's method for controlling unnecessary increases in costs was *ultra vires* and vacated the challenged portion of the 2019 OPPS Rule. ECF No. 32; *see also* ECF No. 39 (denying HHS's motion to modify the Court's September 17, 2019 order and entering final judgment).

On August 9, 2019, before the Court ruled on the parties' cross motions for summary judgment, HHS issued a notice of proposed rulemaking as part of its annual rate-setting process to establish OPPS rates for the 2020 calendar year. *See* 84 Fed. Reg. 39,398. After considering

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comments on the proposed rule, HHS made the final version of the 2020 rule covering the 2020 calendar year available on its website on November 1, 2019, *see* CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC) (Nov. 1, 2019), https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicareprogram-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center (2020 OPPS Rule). The 2020 OPPS Rule was published in the Federal Register on November 12, 2019. *See* 84 Fed. Reg. 61,142.

In the preamble to the 2020 OPPS Rule, HHS acknowledged that this Court vacated its volume control method for the 2019 calendar year and explained that HHS is "working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order." *Id.* at 61,368. As HHS further explained, however, HHS continues to

believe that Section 1833(t)(2)(F) of the Act grants the Secretary the authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and, as a result, is unnecessarily increasing service volume.

Id. at 61367-68. Because HHS still has the right to appeal the Court's judgment, and because the Court vacated only the 2019 OPPS Rule, HHS determined that it would be appropriate to implement the second phase of its volume control methodology in the 2020 OPPS Rule, which would apply only to the 2020 calendar year. *Id.* at 61,368.

On November 11, 2019, Plaintiffs moved to enforce the Court's September 17, 2019 order, which Plaintiffs contend prevents HHS from exercising its Subsection (t)(2)(F) authority in the 2020 OPPS Rule. *See* ECF No. 43 (Judgment Mem.).

ARGUMENT

The Court should deny Plaintiffs' motion to enforce the judgment for two reasons. First, the Court lacks jurisdiction over this motion because it targets the 2020 OPPS Rule and, as to

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that rule, Plaintiffs have not satisfied the unwaivable presentment requirement of 42 U.S.C. § 405(g). Second, the motion lacks merit, because it seeks relief beyond that provided by the Court's judgment, and should therefore be denied. *See Heartland Reg'l Med. Ctr. v. Leavitt*, 415 F.3d 24, 29 (D.C. Cir. 2005).

The Court has jurisdiction to review a challenge to Medicare payment rates only in the "concrete setting of a specific reimbursement decision." Am. Hosp. Ass'n v. Azar, 895 F.3d 822, 827 (D.C. Cir. 2018) (quotation marks omitted). That is, Plaintiffs must submit a "specific administrative claim for payment" under the 2020 OPPS before they can challenge the "new reimbursement regulation." Id. This is known as the presentment requirement. It is a nonwaivable, jurisdictional prerequisite to review, id. at 825, 828; Ryan v. Bentsen, 12 F.3d 245, 247 (D.C. Cir. 1993), which has long-been recognized by the Supreme Court, see, e.g., Shalala v. Ill. Council on Long Term Care, Inc., 529 U.S. 1, 15 (2000) ("[Section] 405(g) contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court."). The doctrine grows out of the language of the Medicare statute: Section 405(g) predicates the availability of judicial review on the issuance of a "decision" by the Secretary, and without presentment, the required decision is lacking. *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976); Am. Hosp. Ass'n, 895 F.3d at 825-26. And importantly, the D.C. Circuit has relied on the doctrine to prevent plaintiffs-including the American Hospital Association (AHA)—from challenging payment rates in rules, including the 2018 OPPS rule, which had not yet taken effect at the time the challenge was raised. Am. Hosp. Ass'n, 895 F.3d at 826 ("When the plaintiffs filed this lawsuit, neither the hospital plaintiffs, nor any members of the hospital-association plaintiffs, had challenged the new reimbursement regulation [*i.e.*, the 2018 OPPS] in the context of a specific administrative claim for payment. Nor could they have

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done so, for the new regulation had not yet even become effective. Therefore, they had [not] presented their claim"); *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1129-33 (D.C. Cir. 1992) (determining that Court lacked jurisdiction because plaintiff failed to secure an "initial administrative determination" in the "concrete setting" of a specific claim for payment).

Plaintiffs have not satisfied the presentment requirement. They have not made a "specific administrative claim for payment" under the 2020 OPPS rule. *Am. Hosp. Ass'n*, 895 F.3d at 827. Nor could they have satisfied this requirement before filing their motion because the 2020 OPPS rule has not taken effect yet. *See* 84 Fed. Reg. at 61,142 ("This final rule is effective on January 1, 2020). This is precisely the position in which AHA (and the other plaintiffs) found themselves in the D.C. Circuit in 2018. In that case, the D.C. Circuit, like the district court before it, concluded that it lacked jurisdiction because Plaintiffs had not satisfied the presentment requirement. *Am. Hosp. Ass'n*, 895 F.3d at 828. This Court should reach the same conclusion here.¹

Plaintiffs anticipated this argument in their motion, but their response is unpersuasive. They state that presentment "should not be a necessary predicate" to "seeking judicial relief," and "[i]nstead, this Court can and should find CMS in violation of its September 2019 Order for continuing forward with the CY 2020 rate reductions 'finalized' in the 2019 OPPS Final Rule that was vacated." Judgment Mem. at 8. But regardless of whether Plaintiffs believe that presentment "should" be a "necessary predicate" to judicial review, it is—and it is not waivable. *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 15; *Am. Hosp. Ass'n*, 895 F.3d at 827; *see also*

¹ The plaintiffs in the consolidated case, *University of Kansas Hospital v. Azar*, appear to recognize that presentment is required before they can challenge the 2020 OPPS Rule. *See* Statement of the *University of Kansas Hospital Authority* Plaintiffs in Response to the *American Hospital Association* Plaintiffs' Motion to Enforce Judgment at 2, ECF No. 44 (indicating that they intend to bring an action "following presentment of their claims to the agency").

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Ryan, 12 F.3d at 247. There is no exception merely because the 2020 OPPS Rule is similar to the 2019 OPPS Rule with respect to the site-neutral payment issue, just as the Supreme Court has held that there is no exception "based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Ill. Council on Long Term Care, Inc.*, 529 U.S. at 13–14. In short, nonwaivable means nonwaivable. And as Plaintiffs have not submitted a "specific administrative claim for payment" under the 2020 OPPS Rule, there is no agency decision under § 405(g), and the Court lacks jurisdiction to vacate a portion of the 2020 rule. *Am. Hosp. Ass'n*, 895 F.3d at 827.

In any case, the motion fails on the merits as well. A "[c]ourt should grant a motion to enforce [a judgment] if a prevailing plaintiff demonstrates that a defendant has not complied with a judgment entered against it." *Yanofsky v. U.S. Dep't of Commerce*, No. 1:16-CV-951 (KBJ), 2019 WL 5110502, at *2 (D.D.C. Apr. 25, 2019) (quotation marks omitted). "Success on a motion to enforce a judgment gets a plaintiff only 'the relief to which [the plaintiff] is entitled under [its] original action and the judgment entered therein." *Heartland Regional Medical Center v. Leavitt*, 415 F.3d 24, 29 (D.C. Cir. 2005) (citing *Watkins v. Washington*, 511 F.2d 404, 406 (D.C. Cir. 1975)).

HHS did not violate the judgment in this case through its promulgation of the 2020 OPPS Rule. The Court's order in this case states, in relevant part, that "the Secretary's Method to Control for Unnecessary Increases in the Volume of Outpatient Services, 83 Fed. Reg. 58,818, 59,004-15 (Nov. 21, 2018) (Section X.B), is VACATED and this matter REMANDED to the Secretary for further proceedings consistent with the Memorandum Opinion." ECF No. 32. In

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other words, the Court vacated and remanded only part of the 2019 OPPS Rule. It did not pass judgment on the 2020 OPPS Rule. Indeed, Plaintiffs did not ask it too. *See* Am. Compl., ECF No. 13; Mem. of Points and Auth. in Support of Pls.' Mtn. for Summ. J., Feb. 1, 2019, ECF No. 14-1. (Nor could they have, given the presentment requirement.) Plaintiffs, then, seek more than the relief they obtained from the Court's Order: The Order vacated the *2019 OPPS Rule* with respect to the agency's approach to site-neutral payments, but Plaintiffs now ask the Court to vacate part of the *2020 OPPS Rule* with respect to the same issue. Plaintiffs' remedial request in their motion lays bare this flaw in their argument: "Plaintiffs . . . request an order finding the CY 2020 reductions unlawful for the same reasons the CY 2019 reductions were unlawful, and vacating the relevant portion of the 2020 OPPS Final Rule." Judgment Mem. at 9. If Plaintiffs were truly seeking an order enforcing the judgment, then they would not have had to request that the Court vacate the relevant portion of an entirely different rule than the one they challenged in this suit.

In their brief, Plaintiffs suggest that this case is special because the 2020 OPPS Rule and the 2019 OPPS Rule are related when it comes to the site-neutral payment policy. Plaintiffs assert that "[t]he agency's conduct in persisting with the two-year phase-in rates 'finalized' in the vacated 2019 OPPS Final Rule was a direct violation of the Court's September 2019 ruling. When a court vacates an agency's annual rate rule, that rule plainly cannot determine subsequent years' rates." Judgment Mem. at 8. This argument is flawed. As an initial matter, Plaintiffs misinterpret the 2019 OPPS Rule. The 2019 OPPS Rule did not adopt the payment rate for services applicable in 2020; it set out the rate that would apply in 2019 and announced the agency's expectation of what the rate would be in 2020. *See* 83 Fed. Reg. at 59,009, 59,011. The agency is obligated to issue a new OPPS rule every year after considering comments

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submitted during the notice and comment process. *See* 42 U.S.C. § 1395*l*(t)(9)(A). Thus, the 2020 rates are determined by the 2020 OPPS Rule. Moreover, as noted above, the promulgation of the 2020 OPPS Rule was not a "direct violation of the Court's September 2019 ruling," because that ruling addressed the 2019 OPPS Rule, not the 2020 Rule. Finally, as to the last point in the text quoted from Plaintiffs' brief, and to reiterate the point made above, the "vacate[d]" 2019 rule is not used to "determin[e the] subsequent year['s] rates": The 2020 OPPS Rule is. The motion should be denied.

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs' motion to enforce the judgment.

Dated: November 25, 2019

Respectfully submitted,

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