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. 1:20-CV-00080-RMC

DEFENDANT'S REPLY IN SUPPORT OF HIS MOTION TO DISMISS OR, IN ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

As Defendant acknowledged in his opening brief, this Court already addressed the parties' arguments in its decision vacating the relevant portion of the United States Department of Health and Human Services (HHS) 2019 Outpatient Prospective Payment System (OPPS) Rule. *See Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 142, 160-61 (D.D.C. 2019) (*AHA I*); *Am. Hosp. Ass'n v. Azar*, Civil Action No. 18-2841 (RMC), 2019 WL 5328814, at *3 (D.D.C. Oct. 21, 2019). However, the government has appealed the Court's decision, and Defendant files the instant reply to preserve its appellate rights with respect to the 2020 OPPS Rule, 84 Fed. Reg. 61,142 (Nov. 12, 2019). For the reasons stated below and in Defendant's opening brief—as well as in Defendant's briefing in *AHA I*—Defendant respectfully submits that Plaintiffs' arguments lack merit and that the Court should dismiss Plaintiffs' claims, or, alternatively, enter judgment in Defendant's favor.

ARGUMENT

I. THE 2020 OPPS RULE IS LAWFUL AND SHOULD BE UPHELD

A. HHS Properly Exercised Its Authority under Paragraph (2)(F)

As Defendant explained in his opening brief, Plaintiffs' claims are precluded by the Medicare statute, and Plaintiffs are therefore forced to resort to a non-statutory *ultra vires* claim. *See* Def.'s Opp'n to Pls.' Mot. for Summ. J, and Cross Mot. to Dismiss or, in the Alternative, for Summ. J. at 5-6, ECF No. 15-1 (Def.'s Opening Br.). Yet, far from being *ultra vires*, the Rule is entirely consistent with Congress's directive to develop a method to control unnecessary increases in the volume of outpatient department services paid through the OPPS. *See id.* 6-9. Plaintiffs argue that HHS lacked the authority to control unnecessary increases in the volume of the relevant services, based on Plaintiffs' reading of the structure and text of the statute. *See* Pls.' Opp'n to Def.'s Mot. to Dismiss or, in the Alternative, for Summ. J. at 2-4, ECF No. 17 (Pls.' Opp'n). But

Defendant acted lawfully, and Plaintiffs fail to show a "patent violation of agency authority," as required to succeed on an *ultra vires* claim. *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs*., 830 F.3d 515, 522 (D.C. Cir. 2016) (citation and internal quotations omitted).

Paragraph (2)(F) of the Medicare statute directs HHS to develop a method to control unnecessary increases in the volume of outpatient department services. *See* 42 U.S.C. § 1395*l*(t)(2)(F). The method that HHS developed in the 2020 OPPS Rule falls well within its statutory authority, for the reasons Defendant has explained. *See* Def.'s Opening Br. at 6-9. "Method" is not defined in the statute, and HHS reasonably interprets the term to include creating parity between the OPPS and equivalent payment rates under the Medicare Physician Fee Schedule (PFS) in order to address an unnecessary increase in volume. *See* 83 Fed. Reg. at 58,818, 59,009 (Nov. 21, 2018); 84 Fed. Reg. at 61,366-67; *see also* Def.'s Opening Br. at 6-7.

Further, paragraph (9)(C) gives HHS the option, after developing a method to control unnecessary costs, to implement an across-the-board adjustment to the conversion factor to reduce overall OPPS costs. 42 U.S.C. § 1395*l*(t)(9)(C). Pointing to paragraph (9)(C), Plaintiffs argue that HHS's paragraph (2)(F) authority *must* be applied as an across-the-board adjustment of the conversion factor. Pls.' Opp'n at 3. But if that were so, Congress would not have said in paragraph (9)(C) that HHS "*may*" adjust the conversion factor. 42 U.S.C. § 1395*l*(t)(9)(C). Such permissive language shows that Congress intended to confer discretion on the agency, and the Court should defer to the agency's determination. *See* Def.'s Opening Br. at 7-8.

Plaintiffs also provide no persuasive explanation for why Congress would authorize the Secretary to "develop a method for controlling unnecessary increases in the volume of covered [outpatient department] services," 42 U.S.C. § 1395*l*(t)(2)(F), and then impose constraints that are so protective of unnecessary services as the ones for which Plaintiffs advocate. Nor do Plaintiffs

explain why Congress would force HHS to arbitrarily reduce rates for other services when HHS has found no such unnecessary increase in volume. *See* Def.'s Opening Br. at 6.[1]

Finally, Plaintiffs argue that HHS violated the APA by issuing a rule that is, in Plaintiffs' view, in tension with HHS's prior statements. *See* Pls.' Opp'n at 6. In support of their argument, Plaintiffs cite *Encino Motocars, LLC v. Navarro*, 136 S. Ct. 2117 (2016). But in that case, the agency had taken a definitive position with respect to the definitions at issue in a decades-old formal opinion letter. *Id.* at 2123. And the Court held that the agency must provide a reasoned explanation before revising those same definitions, "in light of the Department's change in position and the significant reliance interests involved." *Id.* at 2126. The facts in *Encino* are thus far different from the off-hand statements that Plaintiffs cite, *see* Pls.' Opp'n at 4, in which HHS did not purport to take a position on the scope of its paragraph (2)(F) authority. *See* Def.'s Opening Br. at 9.

In any event, in *Encino*—and in *FCC v. Fox v. Television Stations, Inc*, 556 U.S. 502 (2009), on which *Encino* relied—the Court required only that the agency provide a "reasoned explanation" for its position. *See Encino*, 136 S. Ct. at 2126; *Fox*, 556 U.S. at 515-16. And that is precisely what HHS did. The preambles to the 2019 OPPS Rule and the 2020 OPPS Rule provide detailed analysis regarding HHS's interpretation of its paragraph (2)(F) authority, and explain at length why HHS disagreed with commenters who raised precisely the same arguments that Plaintiffs do here. *See* 83 Fed. Reg. at 59,011-13; 84 Fed. Reg. at 61,367-68. Nothing more is required under the APA. *See Encino*, 136 S. Ct. at 2126.

[1] Plaintiffs are also incorrect that the legislative history supports their reading of the statute. *See* Pls.' Opp'n at 3 n.1. The Court need not look to the legislative history, because the text of the statute authorizes HHS's actions. But, even so, the House conference report Plaintiffs cite does not support their claims. *See* Def.'s Opening Br. at 9.

B. The Rule Is Not Contrary to Section 603 of the Bipartisan Budget Act of 2015

Plaintiffs also maintain that Congress created a protected class of hospital providers in Section 603 of the Bipartisan Budget Act of 2015—so-called excepted off-campus PBDs—that are forever protected from any HHS action that affects payment rates for services performed by these providers. *See* Pls.' Opp'n at 4-5. Yet, as Defendant has explained, Plaintiffs give too much weight to the distinction Congress created in Section 603 and choose to minimize HHS's authority under paragraph (2)(F). *See* Def.'s Opening Br. at 9-11. Nothing in Section 603 prevents HHS, after having determined that there has been an unnecessary increase in the volume of specific outpatient department services among providers who remain in the OPPS, from exercising its separate paragraph (2)(F) authority to control the volume of that service. *See id.*

Plaintiffs' emphasis on Section 603 above other aspects of the Medicare statute also proves too much. Under Plaintiffs' theory, the distinction between excepted and non-excepted off-campus PBDs means that Congress meant to forever enshrine higher rates for excepted off-campus PBDs. *See* Pls.' Opp'n at 4-5. Yet, Plaintiffs also point out that HHS "may" adjust the conversion factor to reduce rates for *all* services provided in the OPPS—*i.e.*, those provided by excepted off-campus PBDs. *See, e.g.*, Pls.' Opp'n at 7. Plaintiffs therefore have already acknowledged that HHS *can* reduce rates for excepted off-campus PBDs in the face of unnecessary increases in volume, despite the distinction created by Section 603. Their contrary claim that excepted off-campus PBDs are also somehow untouchable must therefore fail.

To accept Plaintiffs' argument that the Rule is *ultra vires* in light of Section 603, the Court would need to conclude not only that Congress created a distinction between excepted and non-excepted off-campus PBDs, but also that Congress silently forbade HHS from exercising paragraph (2)(F) authority as to excepted off-campus PBDs in any way that would affect the rates they are paid. The Court need not accept Plaintiffs' overly broad interpretation. Had Congress

intended the extreme outcome Plaintiffs suggest, it surely would have explicitly restricted HHS's paragraph (2)(F) authority. But it did not. Rather, Congress left excepted off-campus PBDs subject to HHS's paragraph (2)(F) authority.

Here, HHS used that paragraph (2)(F) authority to address a narrow but serious problem that Section 603 does not address: an unnecessary increase in the volume of clinic visit services provided by excepted off-campus PBDs. Nothing in Section 603 precludes the relevant portion of the 2020 OPPS Rule, and all of the other thousands of services provided by excepted off-campus hospital outpatient departments remain untouched by the Rule—which belies Plaintiffs' claim that HHS is attempting to subvert the distinction Congress created in Section 603.

II. IF PLAINTIFFS PREVAIL, REMAND IS THE APPROPRIATE REMEDY

For the reasons Defendant has explained, if the Court concludes that HHS lacked authority under paragraph (2)(F) to control the unnecessary volume of certain services, the appropriate remedy would be to remand to HHS for further consideration without vacatur. *See, e.g.*, *INS v. Ventura*, 537 U.S. 12, 16 (2002) ("'The proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."' (quoting *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985))); *see also AHA I*, Mot. to Modify Order, ECF No. 33. Contrary to Plaintiffs' claim, Defendant did not "disregard[] this Court's Order" in issuing the 2020 OPPS Rule, *see* Pls.' Opp'n at 5-6. Rather, in promulgating the 2020 OPPS Rule, HHS acknowledged this Court's decision and explained that it would still be appropriate to implement the second phase of the method to control for an unnecessary increase in the volume of services in light of Defendant's appeal to the D.C. Circuit. *See* 84 Fed. Reg. at 61,367-68. That course of action was reasonable given the parties' ongoing legal dispute and in no way supports vacatur as opposed to a remand.

CONCLUSION

For the foregoing reasons, and for the reasons stated in his prior briefing in this case and in *AHA I*, Defendant respectfully requests that the Court grant his motion to dismiss or, in the alternative, for summary judgment.

Dated: March 12, 2020

Respectfully submitted,

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