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 OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT, AND CROSS MOTION TO DISMISS OR, IN ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs challenge the second phase of the development by the United States Department of Health and Human Services (HHS) of a method to control an unnecessary increase in the volume of particular clinic services at outpatient hospital departments that can be provided just as safely, and at lower cost, in a freestanding physician's office. The challenged method is contained in HHS's 2020 rule governing Medicare payments for services provided under the Outpatient Prospective Payment System (OPPS) for the current calendar year. *See* 84 Fed. Reg. 61,142 (Nov. 12, 2019) (2020 OPPS Rule).

Defendant recognizes, of course, that this Court previously concluded that HHS's development of the same method in the OPPS rule governing the 2019 calendar year, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (2019 OPPS Rule), was unlawful and therefore vacated the relevant portion of the 2019 OPPS Rule, *see Am. Hosp. Ass'n v. Azar*, 410 F. Supp. 142, 160-61 (D.D.C. 2019); *Am. Hosp. Ass'n v. Azar*, Civil Action No. 18-2841 (RMC), 2019 WL 5328814, at *3 (D.D.C. Oct. 21, 2019). However, HHS has appealed that decision to the D.C. Circuit, and Defendant files the instant opposition and cross motion to dismiss or, in the alternative, to preserve its appellate rights with respect to the 2020 OPPS Rule, in the event that the Court of Appeals disagrees with this Court's analysis.

As explained below, Plaintiffs' challenge to the 2020 OPPS Rule lacks merit. HHS's development of a methodology to control an unnecessary increase in the volume of particular clinic visit services is consistent with the Medicare statute, including the distinction in the statute between excepted and non-excepted provider-based departments (PBDs). Further, although Defendant recognizes that this Court vacated the analogous portion of the 2019 OPPS Rule,

Defendant respectfully submits that, if the Court rules for Plaintiffs, the appropriate remedy would be to remand to HHS for further consideration without vacatur.

BACKGROUND

A. The 2019 OPPS Rule

Each year, through notice-and-comment rulemaking, HHS establishes the rates that the Medicare program will pay hospitals for the upcoming calendar year through the OPPS. In the 2019 OPPS Rule, HHS exercised its authority under 42 U.S.C. § 1395*l*(t)(2)(F) ("paragraph (2)") to control unnecessary increases in the volume of particular covered outpatient department services. *See* 83 Fed. Reg. at 59,004-15. HHS determined that the growth of certain routine clinic visits at off-campus hospital outpatient departments was due to the differential between the OPPS payment rate and the lower Medicare rate paid under the physician fee schedule. HHS explained that "these services could likely be safely provided in a lower cost setting," *i.e.*, at physician offices. 83 Fed. Reg. 37,046, 37,142 (July 31, 2018). HHS concluded that "capping the OPPS payment at the [physician fee schedule]-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed." 2019 OPPS Rule, 83 Fed. Reg. at 59,009. HHS thus reduced the Medicare payment rate for routine clinic visits for off-campus outpatient departments to equal the rate paid to physicians for the same services, and indicated that the rate reduction would be phased in over two years. *Id*. at 59,014.

The American Hospital Association and various other plaintiff hospitals challenged the 2019 OPPS Rule in *American Hospital Association v. Azar*, No. 1:18-cv-2841 (D.D.C.) (*AHA I*). The *AHA I* plaintiffs moved for summary judgment, *AHA I*, ECF No. 14, and Defendant cross moved to dismiss or, in the alternative, for summary judgment, *AHA I*, ECF No. 21.

On September 17, 2019, this Court granted the *AHA I* plaintiffs' motion, declaring that the rate reduction for routine clinic visits at off-campus outpatient departments was *ultra vires*. *See AHA I*, 410 F. Supp. 3d at 160. The Court concluded that the method adopted by HHS was outside the agency's statutory authority and that, based on other aspects of the OPPS scheme, a volume-control method cannot include "service-specific, non-budget-neutral cuts." *Id.* at 156. In a subsequent order, the Court vacated the relevant portion of the 2019 OPPS Rule. *See AHA I*, 2019 WL 5328814, at *3.

On December 12, 2019, Defendant appealed the Court's decision to the United States Court of Appeals for the D.C. Circuit. *See AHA I*, ECF No. 48. Appellate briefing will be complete on March 12, 2020, *see Am. Hosp. Ass'n v. Azar*, No. 19-5352, Clerk's Order (D.C. Cir. Dec. 18, 2019), and the D.C. Circuit will hear oral argument on April 17, 2020, *see Am. Hosp. Ass'n v. Azar*, No. 19-5352, Clerk's Order (D.C. Cir. Feb. 10, 2020).

B. The 2020 OPPS Rule

On August 9, 2019, before the Court ruled on the parties' cross motions for summary judgment in *AHA I*, 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 comments on the proposed rule, HHS made the final version of the 2020 OPPS Rule 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). HHS published the 2020 OPPS Rule 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 in the 2019 OPPS Rule 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 appealed the Court's judgment, and because the Court vacated only the method developed in 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, the *AHA I* plaintiffs moved to enforce the Court's September 17, 2019 order, which Plaintiffs claimed prevented HHS from exercising its paragraph (2)(F) authority in the 2020 OPPS Rule. *See* ECF No. 43. Defendant opposed that motion, *see AHA I*, ECF No. 45, and, on December 16, 2019, the Court concluded that it lacked jurisdiction over the *AHA I* plaintiffs' request that the Court apply its earlier ruling with respect to the 2020 OPPS Rule, *AHA I*, ECF No. 50.

C. This Litigation

On February 2, 2020, Plaintiffs filed their amended complaint in this action against the Secretary of Health and Human Services in his official capacity. Am. Compl., ECF No. 13. In their amended complaint, Plaintiffs assert that the Plaintiff Hospitals provided services with payment rates affected by the 2020 OPPS Rule after the rule took effect and that they have submitted claims for payment to their Medicare contractors. *Id.* ¶ 17. Plaintiffs further allege that they are being paid according to the rates established by the 2020 OPPS Rule. *Id.*

Plaintiffs assert that the 2020 OPPS Rule is contrary to the Medicare statute, including the distinction between excepted and non-excepted PBDs, and that the Rule is therefore *ultra vires*. *See id.* ¶¶ 72-75. Plaintiffs seek declaratory and injunctive relief (i) preventing Defendant from implementing its method to control unnecessary increases in volume and (ii) requiring HHS to provide payments for OPD services at the pre-Rule OPPS amount. *See id.*, Prayer for Relief. Plaintiffs moved for summary judgment on February 2, 2020. *See* Pls.' Mot. for Summ. J., ECF No. 14.

ARGUMENT[1]

I. HHS LAWFULLY DEVELOPED A METHOD TO CONTROL FOR UNNECESSARY INCREASES IN THE VOLUME OF CERTAIN OUTPATIENT SERVICES.

Plaintiffs contend that the agency misinterpreted the Medicare statute and that, in doing so, will deprive hospitals of millions of dollars in Medicare payments. Am. Compl. ¶¶ 74-75. Such claims are typically brought under the Administrative Procedure Act (APA); however, the APA does not apply . . . 'to the extent that . . . statutes preclude judicial review.'" *Tex. All. for Home Care Servs.*, 681 F.3d at 408 (quoting 5 U.S.C. § 701(a)). Here, the Medicare statute precludes judicial review of a challenge, like Plaintiffs', to the Secretary's development of a method under paragraph (2)(f). 42 U.S.C. § 1395*l*(t)(12)(A).

Plaintiffs are thus forced to resort to a non-statutory *ultra vires* claim. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 112-13 (D.C. Cir. 2004) (stating, in dicta, that it would construe the OPPS

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[1] Plaintiffs' challenge to the 2020 OPPS Rule is substantively identical to their challenge to the 2019 OPPS Rule, and Plaintiffs have largely incorporated by reference their briefing from *AHA I*. *See* Pls.' Mem. of Points & Auth. in Supp. of Pls.' Mot. for Summ. J. at 5 n.2, ECF No. 41-1 (Pls.' Mem.). Defendant follows suit and incorporates by reference his briefing from *ACA I*. *See* Def.'s Opp'n to Pls.' Mot. for Summ. J. & Mem. in Supp. of Mot. to Dismiss or, in the Alternative, Cross-Mot. for Summ. J., *AHA I*, ECF No. 21; Reply in Supp. of Def.'s Mot. to Dismiss or, in the Alternative, Cross-Mot. for Summ. J., *AHA I*, ECF No. 25.

bar on judicial review to allow limited review of claims of *ultra vires* action). To prevail on such a claim, "[plaintiffs] must show a patent violation of agency authority." *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). Here, Plaintiffs' *ultra vires* claim fails because the challenged portion of the 2020 OPPS Rule rests well within the agency's authority, as explained below.

A. HHS ACTED WITHIN ITS STATUTORY AUTHORITY.

In the Rule, HHS properly exercised its statutory authority to develop a method to control unnecessary increases in the volume of particular services paid through the OPPS. *See* 42 U.S.C. § 1395*l*(t)(2)(F). Plaintiffs contend that HHS acted unlawfully, because, according to Plaintiffs, the statute allows rates for specific services to be reduced only if HHS does so in a budget neutral manner through paragraph (9)(C). *See* Pls.' SJ Mem. at 5. Plaintiffs further argue, similarly, that, when exercising its paragraph (2)(f) authority, HHS must "do so across-the-board, to all covered services." *Id.*

Plaintiffs' reading of paragraphs (2)(F) and (9)(C) would lead to results that Congress plainly did not intend. Plaintiffs provide no logical reason why Congress would have wanted HHS to take the draconian step of penalizing everyone in the OPPS system by reducing rates for every type of service in order to control an unnecessary increase in the volume of a single type of service. Nor do Plaintiffs explain why addressing an *unnecessary* increase in the volume of a specific service must be accomplished in a budget-neutral fashion. Rather, much more sensibly, HHS interprets paragraph (2)(F) to allow it to develop a non-budget-neutral method to control unnecessary increases in volume for a specific service, which can include a reduction in rates to eliminate a perverse economic incentive.

HHS's interpretation is supported by the language and structure of the Medicare statute. "Method" is not defined in the statute, and HHS reasonably interprets that 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 59,009. Plaintiffs assert that interpretation is impermissible because—in Plaintiffs' view—paragraph (9)(C) is the only way HHS may exercise its paragraph (2)(F) authority. But Plaintiffs' reading is not supported by the text of the statute.

Paragraph (9)(C) states that the Secretary "*may* appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year" if "the Secretary determines under the methodologies described in [paragraph (2)(F)] that the volume of services paid for under this subsection increased beyond amounts established through those methodologies[.]" 42 U.S.C. § 1395*l*(t)(9)(C) (emphasis added). The language Congress used—that HHS "may" adjust the conversion factor in response to certain findings under paragraph (2)(F)—is entirely permissive and, contrary to Plaintiffs' claim, does not tie HHS's hands to any particular course of action to control unnecessary increases in the volume of OPD services. *See Adirondack Medical Ctr. v. Sebelius*, 740 F.3d 692, 697-98 (D.C. Cir. 2014) (explaining that "Congress generally knows how to use the word 'only' when drafting laws," and that specifying what the Secretary "may" do was more likely Congress's attempt "to clarify what might be doubtful," rather than impose a restriction). Indeed, the permissive nature of HHS's authority under paragraph (9)(C) stands in stark contrast with the directive in paragraph (2)(F) that HHS "shall" control unnecessary volume increases by developing a methodology to control them, further suggesting that HHS has options other than a conversion factor adjustment to implement a methodology (*e.g.*, by reducing payment rates, as HHS did in the Rule).

Plaintiffs are also incorrect when they argue that any changes to payment rates for individual services must be budget neutral if they do not apply across-the-board. The budget

neutrality provision on which Plaintiffs' argument is based, paragraph (9)(B), applies only to the periodic rate adjustments made under paragraph (9)(A). Specifically, paragraph (9)(B) states, "[*i*]*f* the Secretary makes adjustments *under subparagraph (A)*, *then* the adjustments for a year" must be budget neutral. 42 U.S.C. § 1395*l*(t)(9)(B) (emphasis added). The budget neutrality requirement in paragraph (9)(B) does not apply when HHS exercises its separate authority under paragraph (2)(F).

Further, paragraph (2)(F), unlike other similar provisions, does not contain a free-standing budget neutrality requirement. By contrast, in the two paragraphs directly preceding paragraph (2)(F), Congress included a budget neutrality requirement when giving HHS the authority to make certain other payment changes. In paragraph (2)(D), Congress was clear that the Secretary "shall determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions *in a budget neutral manner*." *Id.* § 1395*l*(t)(2)(D) (emphasis added). And, similarly, in paragraph (2)(E), Congress directed the Secretary to "establish, *in a budget neutral manner*" adjustments "as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals." *Id.* § 1395*l*(t)(2)(E) (emphasis added). Congress, therefore, obviously knew how to include a clear directive regarding budget neutrality, but it declined to do so in paragraph (2)(F). Congress's silence in paragraph (2)(F) as to whether HHS's methods to control unnecessary volume increases must be budget neutral—compared with Congress's explicit instruction regarding budget neutrality in other, similar provisions—suggests that Congress left the question of budget neutrality in paragraph (2)(F) to the agency's implementation of that provision.

Plaintiffs also rely on the statute's legislative history to attempt to bolster their arguments that an across the board cut to payments for all services is the only non-budget neutral action available to HHS. *See* Pls.' SJ Mem. at 15 (citing Balanced Budget Act of 1997, H.R. Rep. No. 105-217, at 784 (1997) (Conf. Rep.)). Yet, it is unnecessary to look to legislative history because the statute itself authorizes HHS's actions, for the reasons explained above. *See Halverson v. Slater*, 129 F.3d 180, 187 n.10 (D.C. Cir. 1997). Even so, the House conference report Plaintiffs cite no more supports their claims than the statutory text, for the reasons Defendant explained in *AHA I*. *See AHA I*, ECF No. 21 at 17-18.

Finally, Plaintiffs rely on HHS's prior statements regarding its paragraph (2)(F) authority to suggest that HHS "acknowledged that 'possible legislative modification' would be necessary" to exercise that authority as HHS did here. Pls.' SJ Mem. at 8 (quoting 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998)). Plaintiffs are incorrect. HHS has not previously determined the extent of its authority under paragraph (2)(F). *See AHA I*, ECF No. 21 at 20-21. Yet, HHS has now issued the Rule utilizing its paragraph (2)(F) authority to control unnecessary increases in service volume. And despite this Court's ruling in *AHA I*, Defendant respectfully submits that its exercise of that authority in the 2020 OPPS Rule was lawful.

B. The 2020 OPPS Rule is Consistent with the Statutory Distinction between Excepted and Non-Excepted Off-Campus PBDs.

Plaintiffs' other argument is that the Rule is *ultra vires* because it allegedly conflicts with the distinction in the Medicare statute between excepted and non-excepted PBDs. *See* Pls.' Mem. at 9-10. Plaintiffs are incorrect.

In Section 603 of the Bipartisan Budget Act of 2015, Congress amended the Medicare statute to address, in part, the increasing costs of OPD services by expressly creating a relatively small subset of providers that would be excluded from the OPPS. *See* 42 U.S.C. § 1395*l*(t)(21)(C).

Yet, nothing in the statute prevents HHS, having determined that there has been an unnecessary increase in the volume of a specific OPD service among providers who remain in the OPPS system, from exercising its separate paragraph (2)(F) authority to control the volume of that service.

Notwithstanding the revisions Congress made through Section 603, paragraph (2)(F) still requires HHS to "develop a method for controlling unnecessary increases in the volume of covered OPD services," and services provided by excepted PBDs remain "covered OPD services" following Congress's enactment of Section 603. *See id.* § 1395(t)(21)(B). Nor does HHS's development of a paragraph (2)(F) method to reduce the volume of certain services render the statutory distinction between excepted and non-excepted PBDs "meaningless," as Plaintiffs claim. Pls.' Mem. at 10. Excepted PBDs are paid under the OPPS and received the standard OPPS payment amount for all other items and services normally paid under the OPPS. Conversely, non-excepted PBDs are paid under the PFS for most items and services and receive the site-specific PFS payment rate for those items and services—rates that are usually lower than the OPPS payment rates the excepted PBDs receive. Excepted PBDs thus continue to receive the standard OPPS payment amount for emergency department visits, observation services, x-rays, cardiac catheterizations and every one of the thousands of procedures usually paid under the OPPS, other than the clinic visit, where HHS established payment parity between the amount paid to excepted PBDs under the OPPS and non-excepted PBDs under the PFS.

In other words, the 2020 OPPS Rule targets only a single type of service for which HHS determined that there has been an unnecessary increase in volume that can be provided safely in a non-hospital setting. Thus, notwithstanding Plaintiffs' argument, the distinction created by Section 603 continues to have import. Aside from clinic visit services, which HHS determined have increased unnecessarily in volume and for which the agency accordingly exercised its authority

under paragraph (2)(F), services furnished by providers billing under the OPPS as of November 1, 2015 continue to be paid at higher OPPS rates, while services furnished by providers that were not billing as of November 1, 2015 are paid at lower PFS rates.

II. IF PLAINTIFFS PREVAIL, REMAND IS THE APPROPRIATE REMEDY.

If the Court concludes—as it did in *AHA I* for the 2019 OPPS Rule—that HHS lacked authority under paragraph (2)(F) to control the unnecessary volume of certain services, the proper remedy would not be to enter an injunction vacating the relevant portion of the 2020 OPPS Rule and ordering that HHS change its payment policies and provide immediate payments to Plaintiffs at the pre-Rule rate, as Plaintiffs demand. *See* Am. Compl., Prayer for Relief. Rather, Defendant respectfully submits that the appropriate remedy would be to remand to the agency 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.

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court deny Plaintiffs' motion for summary judgment and grant Defendant's motion to dismiss or, in the alternative, for summary judgment.

Dated: February 18, 2020

Respectfully submitted,

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