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. 1:18-CV-2841-RMC

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

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INTRODUCTION

For years, Plaintiff hospitals benefited from a payment policy that allowed them to operate off-campus facilities as provider-based departments ("PBDs") of hospitals, and to be paid at hospital outpatient rates, instead of the lower rate that applies to free-standing physician practices. This policy created a financial incentive for hospitals to purchase free standing physician practices, convert them to off-campus PBDs, and increase the utilization of clinic visits furnished in these off-campus PBDs. Congress intervened to halt the proliferation of new off-campus PBDs in Section 603 of the Bipartisan Budget Act of 2015 ("Section 603"), Pub. L. No. 114-74, § 603, 129 Stat. 584, 598 (2015), and CMS has now used additional authority granted to it by Congress to control the unnecessary utilization of certain services at the remaining facilities—so-called "excepted off-campus PBDs." It promulgated the Rule, now challenged by Plaintiff hospitals, to neutralize the financial incentive to increase off-campus PBD clinic visits, and thereby eliminate wasteful spending and protect beneficiaries from high out-of-pocket costs. *See* Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Proposed Rule, 83 Fed. Reg. 61,567 (Nov. 30, 2018).

In response to Defendant's cross-motion, Plaintiffs only double down on their arguments (as they have every reason to do given the financial incentives of the prior policy). Plaintiffs' first argument is that if CMS wants to reduce payment rates to address an unnecessary increase in the volume of any service in the Outpatient Prospective Payment System ("OPPS") under 42 U.S.C. § 1395*l*(t)(2)(F), CMS must either (1) make across the board cuts to the payment rates for all services (even ones that have not unnecessarily increased in volume); or (2) make a corresponding increase in the payment rates for other services (even if those services are priced

appropriately). This argument is flawed. It has no basis in the text of the statute and similarly lacks a foundation in logic. Plaintiffs provide no persuasive explanation for why Congress would authorize the Secretary to "develop a method for controlling unnecessary increases in the volume of covered OPD services," 42 U.S.C. § 1395*l*(t)(2)(F), and then impose constraints that are so protective of unnecessary services.

Plaintiffs also argue that Section 603 limits CMS's otherwise broad authority to regulate payment rates, prohibiting the agency from forever acting to eliminate the windfall that accrues to the benefit of off-campus PBDs not encompassed by the 2015 law. Not so. Here again, Plaintiffs' argument lacks a statutory basis and makes hash of the purpose of Section 603, which is to stem the rising costs attributable to unnecessary care provided at off-campus OPDs.

Accordingly, for the reasons stated below and in Defendant's opening brief, the Court should enter judgment in Defendant's favor.

ARGUMENT

I. BY RAISING ONLY A NON-STATUTORY CLAIM, PLAINTIFFS HAVE CONCEDED THAT CMS ACTED WITHIN ITS STATUTORY AUTHORITY

In the opening brief, Defendant explained the problem with Plaintiffs' attempt to invoke this Court's non-statutory review authority. Def.'s Opening. Br. at 10-13, ECF No. 20. The problem, in a nutshell, is that Plaintiffs' claim is self-defeating. Non-statutory review is available only if statutory review is unavailable, and if statutory review is unavailable here—because of the effect of the statutory preclusion provision, 42 U.S.C. § 1395*l*(t)(12)(A)—then, by extension, Plaintiffs have conceded that the agency acted within the scope of its statutory authority. *See* Def.'s Opening Br. at 10-13; *COMSAT Corp. v. F.C.C.*, 114 F.3d 223, 227 (D.C. Cir. 1997) (recognizing that a preclusion provision applied only if the FCC acted within the

scope of its jurisdiction).[1] The reason for this is that the preclusion provision applies *only if* the agency acted within the scope of its authority. *See, e.g., Amgen*, 357 F.3d at 113.

Plaintiffs, in response, invoke the idea of a catch-22: "In other words, if a plaintiff challenges the agency as having acted *ultra vires*, it effectively concedes that the agency did not act *ultra vires*. That is a perfect Catch-22." Pls.' Opp'n at 11, ECF No. 22. But there is no inescapable dilemma, no catch-22. In fact, another WWII-related term more accurately describes the situation Plaintiffs finds themselves in: snafu.[2] Plaintiffs could have—and, as a procedural matter, should have—raised a claim under the Administrative Procedure Act that the agency was acting in excess of its statutory authority, *see* 5 U.S.C. § 706(2)(C), as the plaintiffs in the *University of Kansas Hospital Authority* case have done. *See Univ. of Kansas Hosp. Auth. v. Azar*, 1:19-cv-132 (D.D.C.), Second Am. Compl., ECF No. 15, ¶¶ 51-63.[3] If they had done so, Defendant would have argued (correctly) that such a claim is precluded (as well as unfounded). *See Univ. of Kan. Hosp. Auth.,* No. 1:19-cv-132, ECF Nos. 16, 17. But notwithstanding Defendant's argument, Plaintiffs would have had the chance to argue that the preclusion

[1] *See Amgen, Inc. v. Smith,* 357 F.3d 103, 113 (D.C. Cir. 2004) ("If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective, but it must determine whether the challenged agency action is of the sort shielded from review. . . In such cases, the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the preclusion on judicial review.")

[2] https://www.merriam-webster.com/dictionary/snafu.

[3] The University of Kansas Hospital Authority complaint uses the term "*ultra vires*," *see* Second Am. Compl., 19-cv-132, ¶ 62, but that term can be used in the context of APA claims. *Adamski v. McHugh*, 304 F. Supp. 3d 227, 236 (D.D.C. 2015) ("Specifically, when a plaintiff contends that a particular agency action is 'not in accordance with law' under 5 U.S.C. § 706(2)(A) or 'in excess of statutory jurisdiction, authority, or limitations, or short of statutory right' under 5 U.S.C. § 706(2)(C), courts sometimes characterize these statutorily-based assertions as '*ultra vires*' claims.").

provision does not apply because the agency is, in their view, acting outside the scope of its authority. *See Amgen*, 357 F.3d at 113. And if the Court had agreed with Plaintiffs, then it would have concluded that it had jurisdiction to review their APA claim. Plaintiffs, however, sought to avoid this jurisdictional fight by raising a non-statutory claim. And that was their mistake. They did not account for the fact that, due to the limited availability of non-statutory review, its invocation in this circumstance would, by necessity (given its connection to a preclusion provision that applies only if the agency is acting within the scope of its authority), constitute a concession that the agency did not act in an *ultra vires* fashion.

Plaintiffs make two other arguments in their response brief, but neither has merit. First, they argue that two recent district court decisions authorized the sort of non-statutory *ultra vires* claim Plaintiffs raise here. *See* Pls.' Opp'n at 12; *Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 62, 83 (D.D.C. 2018); *H. Lee Moffitt Cancer Ctr. & Research Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 12 (D.D.C. 2018). But the complaints in those cases raised only statutory claims. Complaint, *H. Lee Moffitt Cancer Ctr.*, 1:16-cv-02337, ECF No. 1 (D.D.C. Nov. 28, 2016), ¶¶ 24-40; Complaint, *Am. Hosp. Ass'n*, 1:18-cv-02084, ECF No. 1 (D.D.C. Sept. 5, 2018), ¶¶ 67-78. Accordingly, the courts did not hold that non-statutory review claims were appropriate. *See H. Lee Moffitt Cancer Ctr.*, 324 F. Supp. 3d at 12 (holding that preclusion provision is inapplicable by its terms); *Am. Hosp. Ass'n,* 348 F. Supp. 3d at 78 (same). Second, Plaintiffs contend that "[t]he Government's preclusion argument presumes that Congress's statutory limits on judicial review of Medicare challenges apply to non-statutory claims." Pls.' Opp'n at 13. Defendant, however, has not argued that Plaintiffs' non-statutory claim is precluded. Instead, Defendant asserts that the claim necessarily lacks merit (and Plaintiff has implicitly conceded as

much) because a non-statutory claim is available, in these circumstances, only if the agency acted within the scope of its authority. *See* Def.'s Opening Br. at 12-13.

II. THE RULE IS LAWFUL AND SHOULD BE UPHELD.

Plaintiffs' latest brief illustrates their fundamental misreading of the Medicare statute. Plaintiffs continue to insist that, if CMS wants to reduce payment rates to "control[] unnecessary increases in the volume of [any] covered [hospital outpatient department ("OPD")] service[s]," 42 U.S.C. § 1395*l*(t)(2)(F), it must either (1) make across the board cuts to the rates for all services; or (2) *increase* rates for other services to achieve budget neutrality, even if CMS has no reason to do so. Plaintiffs' interpretation finds no support in the text or purpose of the statute.

A. CMS Properly Exercised Its Authority Under Subsection (t)(2)(F)

As Defendant explained in his opening brief, the Rule is entirely consistent 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 Opening Br. 14-21. Plaintiffs understandably wish that CMS lacked the authority to control unnecessary increases in volume because those unnecessary increases have allowed hospitals to profit mightily by providing services in the more expensive off-campus PBD setting that can safely be performed in the less costly physician's office setting. But Plaintiffs fail to show that CMS acted unlawfully.

Plaintiffs' argument boils down to the following: Congress intended to prevent CMS from reducing rates for any specific service that CMS determines has unnecessarily increased in volume, unless CMS also arbitrarily reduces the rates for other (necessary) services by altering the conversion factor. But why would that be? Such a requirement would effectively prevent CMS from ever addressing an unnecessary increase in the volume of services, and CMS's Subsection (t)(2)(F) authority would serve no useful function. Under Plaintiffs' interpretation,

CMS has no choice but to allow unnecessary increases in volume to continue to drive up Medicare costs indefinitely, or else arbitrarily reduce rates for other services where CMS has found no such unnecessary increase in volume. Fortunately, Congress did not enact such an irrational statute.

Subsection (t)(2)(F) directs CMS to develop a method to control unnecessary increases in the volume of OPD services paid through the OPPS. Subsection (t)(9)(C) further states that, after developing a method to control unnecessary costs, CMS "may" 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 that language, Plaintiffs say that CMS's Subsection (t)(2)(F) authority "*must* be applied as an across-the-board adjustment of the conversion factor." Pls.' Opp'n at 2 (emphasis added). But if that's so, why did Congress say that CMS "*may*" adjust the conversion factor? 42 U.S.C. § 1395*l*(t)(9)(C). Such permissive language, as Defendant has explained, shows that Congress intended to confer discretion on the agency and the Court's should defer to the agency's determination. *See* Def.'s Opening Br. at 16 (citing *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1401 (D.C. Cir. 1995)).

To avoid CMS's textual, common-sense interpretation, Plaintiffs claim that CMS's position is based on "logical fallacies." Pls.' Opp'n at 3. Plaintiffs point out that an increase in utilization *could* result from increased need for those services. *See id*. at 3. Fair enough. But in other scenarios, as Congress recognized, the increase in utilization is "unnecessary," 42 U.S.C. § 1395*l*(t)(2)(F), and Congress gave CMS the authority to make that determination, *id.* Here, CMS determined based on its expertise and the available data that the increase in volume is unnecessary. 83 Fed. Reg. 59,818, 59,007 (Nov. 21, 2018); *see also* Def.'s Opening Br. at 5-8 (discussing the extraordinary increase in the volume of OPD services as a whole and, in

particular, clinic visit services, which has been documented by the Medicare Payment Advisory Commission, among other observers). CMS therefore properly exercised its authority to develop a method to control that unnecessary volume increase. That decision was perfectly logical and consistent with the statute.

Plaintiffs also make some suggestion that CMS's finding that there has been an unnecessary increase in the volume of OPD clinic services was incorrect because "[p]atients who visit off-campus PBDs and those who visit physician offices are not fungible." Pls.' Opp'n at 3. Yet, CMS considered Plaintiffs' objection that patients treated at off-campus PBDs may be sicker than those treated at physician offices, 83 Fed. Reg. at 59,012, and CMS limited the effect of the Rule only to clinic visit services, which can be safely be performed in the lower cost physician office setting, *id*. at 59,008-09. Plaintiffs' half-hearted efforts to show that CMS erred do not render the Rule *ultra vires*. And, in any event, Plaintiffs' concede that "this Court need not decide whether the Government actually found an unnecessary increase in the volume of clinic visit." Pl.'s Opp'n at 4.

Rather than pressing CMS on its findings, Plaintiffs engage in interpretive gymnastics to try to explain why, in Plaintiffs' view, Congress did not actually intend to give CMS discretion as to how to use its authority under Subsection (t)(2)(F) when it used the word "may" in Subsection (t)(9)(C). *See* Pls.' Opp'n at 5. Plaintiffs contend that it is "implicit" in Subsection (t)(9)(C) that the only way CMS can exercise its Subsection (t)(2)(F) authority is to adjust the conversion factor. *Id.* But this Court should not assume "implicit" limitations on CMS's authority that are not clear from the statute. Rather, the Court should defer to CMS's reasonable interpretation to fill gaps in the text. *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 173 (2007). This is particularly true in the context of Medicare in light of Congress's

exceptionally broad delegation of authority to the Secretary to administer the Medicare program, as well as the statute's extreme complexity. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417-20 & n.13 (1993).

If Congress had actually intended to make sure that CMS did not use its Subsection (t)(2)(F) authority to reduce the payments for a specific service, it could have done so. For example:

- Congress could have—as Plaintiffs acknowledge, *see* Pls.' Opp'n. at 5—said that CMS may exercise its Subsection (t)(2)(F) authority "only" through the adjustment factor described in Subsection (t)(9)(C).
- Congress could have stated that Subsection (t)(2)(F) may not be used with respect to specific services.
- Congress could have defined the term "method" in such a way as to preclude creating rate parity between similar types of services.

Or Congress could have expressed Plaintiffs' preferred outcome in any number of other ways. The point, which Plaintiffs cannot escape, is that the provisions at issue are, at the very least, ambiguous, meaning that the Court should defer to CMS's reasonable interpretation. *See Long Island Care at Home*, 551 U.S. at 173.

Plaintiffs also completely distort core principles of administrative law when they claim that CMS violated the APA by issuing a rule that is, in Plaintiffs' view, in tension with CMS'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 a far cry from the off-hand statements that Plaintiffs cited in their opening brief, *see* Pls.' SJ Mem. at 16, in

which CMS did not purport to take a position on the scope of its Subsection (t)(2)(F) authority, *see* Medicare Program; Changes to the Hospital Outpatient Prospective Payment System for Calendar Year 2002, Final Rule, 66 Fed. Reg. 59,856, 59,908 (Nov. 30, 2011) (stating only that Subsection (t)(9)(C) "authorizes" the Secretary to adjust the update to the conversion factor, without stating that an updated conversion factor is the only way to address unnecessary services under (t)(2)(F)); Medicare Program; Prospective Payment System for Hospital Outpatient Services, Proposed Rule, 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998) (referring only to the "possib[ility]" that "legislative modification would be necessary" in order to adopt MedPAC recommendations). Plaintiffs also do not attempt to show that they somehow relied on CMS's prior statements such that the principles from *Encino* could apply here.

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 CMS did. The preamble to the Rule provides detailed analysis regarding CMS's interpretation of its Subsection (t)(2)(F) authority, and explains at length why CMS disagreed with commenters who raised precisely the same arguments that Plaintiffs do here. *See* 83 Fed. Reg. at 59,011-13. Nothing more is required under the APA. *See Encino*, 136 S. Ct. at 2126.

Plaintiffs claim, finally, that CMS's interpretation renders the budget-neutrality provision in Subsection (t)(9)(B) meaningless. *See* Pls.' Opp'n at 7-8. Not at all. The budget neutrality provision clearly applies when CMS makes the type of payment-rate adjustments referenced in Subsection (t)(9)(A)—*e.g.*, wage adjustments, equitable payment adjustments, etc. *See* 42 U.S.C. § 1395*l*(t)(9)(B). Moreover, when CMS develops a method to control an increase in

volume under Subsection (t)(2)(F), CMS's authority is cabined by the requirement that CMS find the increase to be "unnecessary." 42 U.S.C. § 1395*l*(t)(2)(F). As Defendant has explained, it is only natural and consistent with Congress's goal of controlling public expenditures that any method developed under Subsection (t)(2)(F) would be free from the constraint of budget neutrality and that the method employed would be specific to services for which there has been an unnecessary increase in volume. Otherwise, CMS would be forced to increase the payment rates for other services, even if such an increase was not justified, or to allow unnecessary services to continue to drive up costs to Medicare irreversibly. *See* Def.'s Opening Br. at 20. There is simply no basis in the statute to impose this false choice on CMS.

B. The Rule Is Not Contrary to Section 603

Plaintiffs also maintain Congress created a protected class of hospital providers—so-called excepted off-campus PBDs—that are now and forever protected from any CMS action that affects payment rates for services performed by these providers. *See* Pls.' Opp'n at 8-10. Plaintiffs, however, continue to give far too much weight to the distinction Congress created in Section 603 and choose to minimize CMS's authority under Subsection (t)(2)(F). As Defendant has explained, nothing in Section 603 prevents CMS, after having determined that there has been an unnecessary increase in the volume of a specific OPD services among providers who remain in the OPPS, from exercising its separate Subsection (t)(2)(F) authority to control the volume of that service. Def.'s Opening Br. at 22-23.

Plaintiffs' emphasis on Section 603 above other aspects of the Medicare statute also proves too much and is ultimately self-defeating. 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 8-11. Yet, Plaintiffs also point out that CMS "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 1, 2, 4. Plaintiffs therefore have already acknowledged that CMS *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.

Plaintiffs also contend that, had Congress intended to give CMS the authority to control unnecessary increases in volume for services provided by excepted off-campus PBDs, despite the distinction created in Section 603, Congress would have said so. *See* Pls.' Opp'n at 9. Defendant agrees, and Congress did just that. When Congress amended the definition of "covered OPD services" in Section 603, it removed certain off-campus PBDs from the OPPS. But those that remain, excepted off-campus PBDs, continue to be paid under the OPPS and therefore remain subject to CMS's authority to administer that system. That includes the authority under Subsection (t)(2)(F) to develop method to control unnecessary increases in the volume of covered OPD services. 42 U.S.C. § 1395*l*(t)(2)(F).

To accept Plaintiffs' contrary 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 CMS from exercising Subsection (t)(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' incredibly broad interpretation of Congress's action. Had Congress intended the extreme outcome Plaintiffs suggest, it surely would have explicitly restricted CMS's Subsection (t)(2)(F) authority. But it did not. Rather, Congress left excepted off-campus PBDs subject to CMS's Subsection (t)(2)(F) authority. Plaintiffs' arguments therefore fail.

Here, as Defendant has already explained, CMS used its Subsection (t)(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 in the excepted off-campus PBD. Nothing in Section 603 precludes the Rule, and all of the other thousands of services provided by OPDs remain untouched by the Rule—which belies Plaintiffs' claim that CMS is attempting to subvert the distinction Congress created in Section 603.

III. IF THE COURT WERE TO CONCLUDE THAT THE RULE IS UNLAWFUL, REMAND IS THE ONLY APPROPRIATE RELIEF

For the reasons stated above and in Defendant's opening brief, the Court should reject Plaintiffs' challenge to the Rule. However, if the Court were to agree with Plaintiffs' on the merits, it still must consider the appropriate remedy.

Plaintiffs initially claimed that the Court should "order[] that Defendants [*sic*] provide immediate payment of any amounts improperly withheld as a result of the unauthorized conduct described" in their Complaint. *See* Am. Compl., Prayer for Relief, ECF No. 13. To the extent Plaintiffs still envision the court ordering specific payments or directing CMS to take some specific regulatory action on remand, the Court is not authorized to provide that relief. *See* Def.'s Opening Br. at 24-25; *see also, e.g.*, *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005); *INS v. Ventura*, 537 U.S. 12, 16 (2002). Plaintiffs assert vaguely that CMS's hands are now tied and that remand would be futile, but Plaintiffs do not come close to demonstrating that this case falls within the "rare circumstances" where remand is the not the proper course. *Ventura*, 537 U.S. at 16.

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court dismiss this case. In the alternative, Defendant asks that the Court enter summary judgment in his favor.

Dated: April 19, 2019

Respectfully submitted,

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