IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNIVERSITY OF KANSAS HOSPITAL AUTHORITY, *et al.*, Plaintiffs, v. ALEX M. AZAR II, in his official capacity as Secretary of Health & Human Services, Defendant.	Case No. 1:19-CV-132-RMC

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

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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 locations. 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 separate authority granted to it by Congress to control the unnecessary utilization of a narrow class of services at the remaining off-campus PBDs. CMS 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.

In response to Defendant's motion to dismiss and cross-motion for summary judgment, Plaintiffs only double down on their arguments (as they have every reason to do, given the financial incentives of the prior policy). Plaintiffs argue that the excepted off-campus PBDs that Congress allowed to remain in the Outpatient Prospective Payment System ("OPPS") are now essentially untouchable. In Plaintiffs' view, Section 603 limits CMS's otherwise broad authority to regulate their 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. Plaintiffs' argument lacks a statutory basis and makes hash of CMS's authority to control unnecessary increases in the volume of services.

Plaintiffs also argue that, if CMS wants to reduce payment rates to address an unnecessary increase in the volume of any service in the OPPS under 42 U.S.C. § 1395*l*(t)(2)(F) ("Subsection (t)(2)(F)"), CMS must either (1) make across the board cuts to the rates for all services (even ones that have not unnecessarily increased in volume); or (2) make a corresponding increase in the 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 [hospital outpatient department ("OPD")] services," 42 U.S.C. § 1395*l*(t)(2)(F), and then impose constraints that are so protective of unnecessary services.

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

ARGUMENT

I. THE MEDICARE STATUTE PRECLUDES JUDICIAL REVIEW OF PLAINTIFFS' CLAIMS

Defendant explained in his opening brief that 42 U.S.C. § 1395*l*(t)(12)(A) precludes review of claims, like Plaintiffs', challenging CMS's exercise of its authority to "develop a method for controlling unnecessary increases in the volume of covered OPD services" under 42 U.S.C. § 1395*l*(t)(2)(F). Plaintiffs predictably disagree, arguing that § 1395*l*(t)(12)(A) does not apply, because the agency acted outside the scope of its method-development authority. Pls.' Opp'n at 4. This argument fails. Section 1395*l*(t)(12)(A) "merges consideration of the legality of the [agency's] action with consideration of this court's jurisdiction." *COMSAT Corp. v. F.C.C.*, 114 F.3d 223, 227 (D.C. Cir. 1997). As demonstrated throughout this brief and in Defendant's opening brief, CMS's action falls well within the scope of its statutory authority.

Because the agency acted within the scope of its authority, § 1395*l*(t)(12)(A) applies, precluding judicial review and, thereby, depriving the Court of jurisdiction over this action.

II. PLAINTIFFS FAILED TO EXHAUST THEIR ADMINISTRATIVE REMEDIES

Even if 42 U.S.C. § 1395*l*(t)(12)(A) does not preclude review, the Court lacks jurisdiction because Plaintiffs have not exhausted their administrative remedies as required by 42 U.S.C. § 405(g). *See* Def.'s Opening Br. at 13-14, ECF No. 16. Plaintiffs contend that the Court should waive the requirement because exhaustion would be futile, given that the contractors and agency officials who would perform the administrative review are bound by CMS's position. Pls.' Opp'n at 4-7.

But Section 405(g)'s final decision requirement is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility." *Weinberger v. Salfi*, 422 U.S. 749, 766 (1975). Accordingly, "[t]he fact that the agency . . . may lack the power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency." *Shalala v. Illinois Council on Long Term Care, Inc*., 529 U.S. 1, 23 (2000). And, to account for situations like this one, Congress created an abbreviated administrative review process for those cases in which the administrative appeals tribunal "does not have the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute." 42 U.S.C. § 1395*ff*(b)(2)(A). This truncated administrative review process establishes a path to expedited judicial review. Plaintiffs have not availed themselves of this process. Accordingly, they have not exhausted the necessary administrative remedies.

III. THE RULE IS LAWFUL AND SHOULD BE UPHELD

A. CMS Retains Authority to Control Unnecessary Increases in the Volume of Clinic Visit Services Provided by Excepted Off-Campus PBDs

Plaintiffs' opposition illustrates their fundamental misreading of the Medicare statute. In Plaintiffs' view, Congress created a protected class of hospital providers—so-called "excepted off-campus PBDs"—that are now and forever insulated from any CMS action that would affect the rates at which CMS pays them. *See* Pls.' Opp'n at 8-10. Plaintiffs, however, give far too much weight to Congress's decision in Section 603 to keep excepted off-campus PBDs within the OPPS. Although Plaintiffs understandably wish it were so, Section 603 is not a magical talisman that protects excepted off-campus PBDs from rate reductions for all services for all time, no matter what the circumstances.

Section 603 separated off-campus PBDs into two groups, one that would continue to be paid under the OPPS and one that would be paid through the Medicare Physician Fee Schedule ("PFS"). It is true that payment rates for services paid for through the OPPS are higher than those paid for through the PFS. And, indeed, after taking the Rule into account, excepted off-campus PBDs will continue to receive the same OPPS rate for every one of the thousands of services they provide *except* for clinic visit services. Contrary to Plaintiffs' claim, nothing in Section 603 prevents CMS—after having determined that there has been an unnecessary increase in the volume of clinic visit services specifically—from exercising its separate Subsection (t)(2)(F) authority to address that particularized concern. *See* Def.'s Opening Br. at 22-23.

Plaintiffs' argument that Congress meant to protect forever payment rates for all services provided by excepted off-campus PBDs fails for many reasons, not least because it is internally inconsistent. Plaintiffs acknowledge—as they must—that Congress gave CMS the authority elsewhere, in Subsection (t)(9)(C), to adjust the conversion factor that affects payment rates for

"all covered OPD services." *See* Pls.' Opp'n at 14 (citing 42 U.S.C. § 1395*l*(t)(9)(C)). "Covered OPD services," moreover, include those provided by excepted off-campus PBDs (*i.e.*, the group that Congress allowed to remain in the OPPS through Section 603). *See* 42 U.S.C. § 1395*l*(t)(21)(B). Thus—despite their many pages of argument about how Congress "Unambiguously Provided that Excepted Off-Campus Hospital Department Must Be Paid at OPPS Rates," Pls.' Opp'n at 7-12,[1] and how Congress intended to "preserv[e] OPPS payment rates for existing off campus hospital departments," *id.* at 10—Plaintiffs have inescapably conceded that CMS may reduce payment rates to excepted off-campus PBDs if it determines that there is an unnecessary increase in the volume of services.

Plaintiffs quibble that, if CMS exercises its Subsection (t)(2)(F) authority, then it must do so for all services pursuant to Subsection (t)(9)(C) rather than just for those services that it determines are unnecessary. *See* Pls.' Opp'n at 14. That is incorrect, as discussed below and in Defendant's opening brief. *See* Part III.B *infra*: Def.'s Opening Br. at 20-21. But the larger point here is that, while Congress determined that excepted off-campus PBDs should continue to be paid under the OPPS, CMS indisputably still has authority to reduce payment rates within that system for covered OPD services. *See* 42 U.S.C. § 1395*l*(t)(9)(C). Thus, whatever Plaintiffs say about the "balance" Congress struck, Congress did not enshrine any specific payment rate for any particular service for all time. Plaintiffs' arguments based on the purported "special" status of excepted off-campus PBDs therefore fail.

Plaintiffs also argue that the Rule is unlawful because CMS allegedly ignored Congress's concern for vulnerable populations, which Plaintiffs contend is reflected in Section 603. Pls.'

[1] Plaintiffs are incorrect to suggest that excepted off-campus PBDs are no longer paid at OPPS rates for clinic visit services. Those providers are still paid at OPPS rates; however, CMS exercised its Subsection (t)(2)(F) authority to reduce the OPPS rates for those specific services.

Opp'n at 9. To be sure, Congress cares about Medicare beneficiaries, as does CMS, which promulgated the Rule in part to protect those beneficiaries from higher copays for clinic visits performed at excepted off-campus PBDs, *see* 83 Fed. Reg. 58,818, 59,007 (Nov. 21, 2018). But by claiming that Congress meant to protect *all* the payment rates for all of the thousands of services provided by excepted off-campus PBDs in perpetuity, even in the face of an unnecessary increase in the volume of just one those services, Plaintiffs read much more into Congress's intent than the statutory text will bear.

Indeed, to advance their argument, Plaintiffs are forced to resort to sleight of hand. Plaintiffs purport to describe what Congress "recognized in Section 603," but, for support, they point to the statement of a hospital industry representative, expressed at a hearing alongside competing views. *See* Pls.' Mem. at 8 (citing *Hearing with MedPAC to Discuss Hospital Payment Issues, Rural Health Issues, and Beneficiary Access to Care: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 114th Cong. 38 (2015) (statement of the Am. Hosp. Ass'n)). Then, when describing what Congress was "aware" of, Plaintiffs point to an advocacy letter submitted by the American Association of Medical Colleges. *See* Pls.' Opp'n at 8 (citing Letter from Atul Grover, Chief Pub. Policy Officer, Ass'n of American Medical Colleges, to the Honorable John Barrasso, et al. (Jan. 13, 2012)). But industry representatives and advocacy organizations do not speak for Congress. To determine whether CMS lawfully exercised its authority, the Court must look at the legislation Congress actually passed, which unambiguously left CMS with the authority to develop methods to control unnecessary increases in the volume of services paid through the OPPS. *See* 42 U.S.C. § 1395*l*(t)(2)(F).

Plaintiffs also note that Congress has twice addressed payment rates for non-excepted off-campus PBDs—once in Section 603 and again in the 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016)—and Plaintiffs accuse CMS of ignoring the latter legislation. Pls.' Opp'n at 9. The 21st Century Cures Act, however, does not support Plaintiffs' arguments any more than Section 603 does. As relevant here, that statute simply extended excepted off-campus PBD status to certain hospitals that were "mid-build" when Congress enacted Section 603. Like Section 603, it did not purport to set in stone the rates CMS must pay to excepted off-campus PBDs for all services for all time. Plaintiffs fail to show how the 21st Century Cures Act undermines the Rule. If anything, the fact that Congress *twice* addressed the issue of payment to off-campus PBDs and *twice* left in place CMS's authority to control unnecessary increases in the volume of services under Subsection (t)(2)(F) only underscores that the Rule is lawful.

To accept Plaintiffs' argument that the Rule is *ultra vires* in light of Section 603, the Court would need to conclude that, when Congress created a distinction between excepted and non-excepted off-campus PBDs, it also silently forbade CMS from exercising its Subsection (t)(2)(F) authority over excepted off-campus PBDs in any way that would affect the rates at which they are paid. The Court should reject this implausible proposition. 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 PBDs subject to CMS's Subsection (t)(2)(F) authority. Plaintiffs' arguments therefore fail.

Plaintiffs also take issue with Defendant's characterization of their argument as a version of the *expressio unius* canon, *see* Pls.' Opp'n at 10-11, but Plaintiffs miss the point. The parties agree on the principle that "the specific governs the general." Pls.' Opp'n at 11 (citing *RadLAX*

Gateway Hotel, LLC v. Amalgamated Bank, 556 U.S. 639, 654 (2012)). Yet, Plaintiffs apply that principle incorrectly and therefore reach the wrong conclusion. In Section 603, Congress made a broad, generalized determination that excepted off-campus PBDs should remain within the OPPS. Accordingly excepted off-campus PBDs continue to be paid within the OPPS, and—on the whole—they are paid at significantly higher rates than non-excepted off-campus PBDs, which are paid through the PFS. But Congress's broad generalization in Section 603 does not mean that excepted off-campus PBDs must be paid any a specific payment rate in every instance in perpetuity. Here, as Defendant has already explained, CMS used its Subsection (t)(2)(F) authority, which Congress retained in Section 603, to address the narrower, specific issue of an unnecessary increase in the volume of one specific type of service. Plaintiffs themselves acknowledge the Rule's narrow scope: "The Final Rule applies to one specific HCPCS code that providers [ ] use to report [evaluation and management] services performed at excepted off-campus hospital outpatient departments." Pls.' Opp'n at 20. Nothing in Section 603 precludes CMS's action, and the Rule leaves untouched all of the other thousands of services provided by excepted off-campus PBDs—which continue to be paid at the same OPPS rates as the main departments of hospitals. The Rule is thus entirely consistent with Section 603.

B. CMS Properly Exercised Its Authority Under Subsection (t)(2)(F) to Develop a Method to Address an Unnecessary Increase in the Volume of Clinic Visit Services Provided in the Excepted Off-Campus PBD Setting

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. at 20-26. 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 that can safely be performed in the physician office setting instead of in the more expensive off-campus

PBD setting. But Plaintiffs fail to show that CMS exceeded its authority under Subsection (t)(2)(F).

Plaintiffs again assert in their latest brief that CMS is not allowed to apply a method under its Subsection (t)(2)(F) authority to any specific OPD service. *See* Pls.' Opp'n at 12-16. Plaintiffs go long on attempting to describe the complicated interplay between different provisions of the Medicare statute, but their argument boils down to the following: Congress intended to prevent CMS from reducing rates for any specific service, unless it also arbitrarily reduces rates for other services (by changing the conversion factor update). *See id.* at 13-15. But why would that be? Such a requirement would effectively prevent CMS from ever addressing an unnecessary increase in the volume of any specific service, and CMS's Subsection (t)(2)(F) authority would serve no useful function. Under Plaintiffs' interpretation, CMS has no choice but to allow increases in volume to continue to drive up the costs of Medicare 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.

Turning to the text: Subsection (t)(2)(F) directs CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F). Plaintiffs now appear to have abandoned their argument that CMS's actions do not fall within the dictionary definition of what constitutes a "method." *Compare* Pls.' Opening Br. at 23-24; *see also* Def.'s Opening Br. at 22-23 (responding to Plaintiffs' argument). Instead, Plaintiffs raise a new argument. They now assert that, because Subsection (t)(2)(F) refers to "covered OPD services," plural, which is a defined term, *id.* at § 1395*l*(t)(1)(B), CMS may not implement a method to address an unnecessary increase in the volume of any one covered OPD service, singular. *See* Pls.' Mem. at 12-13. This hyper technical and cramped reading of the

Medicare statute cannot save Plaintiffs' case. While Plaintiffs are correct that Subsection (t)(2)(F) refers to "services," the increase in the volume of any one OPD service necessarily contributes to an increase in the volume of OPD services overall. In other words, volume is cumulative. Moreover, even assuming that a finding with respect to clinic visit services were not enough, CMS explicitly considered the effect that the unnecessary increase in the volume of clinic visit services has on the volume of OPD services as a whole. *See, e.g.*, 83 Fed. Reg. 59,005-07. Thus, whether the Court looks to CMS's determination that the increase in the volume of clinic visit services specifically was unnecessary, or to its analysis of that the volume services provided by excepted off-campus PBDs overall, CMS's action is comfortably within its statutory authority either way.

Pointing to Subsection (t)(9)(C), Plaintiffs also continue to insist that the only way CMS may control volume is through the across-the-board adjustment measure contemplated in Subsection (t)(9)C). *See* Pls.' Opp'n at 14. But if that's so, Congress would not have said that CMS "*may*" adjust the conversion factor *after* implementing a method for controlling volume. 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 that the Court should defer to the agency's determination. *See* Def.'s Opening Br. at 21 (citing *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1401 (D.C. Cir. 1995)). And, of course, Congress's decision to allow CMS to address unnecessary increases in volume through means other than across-the-board indiscriminate cuts should come as no surprise, because any alternative reading would lead to absurd results. *See* Def.'s Opening Br. at 20-21.

Plaintiffs further accuse CMS of improperly using its Subsection (t)(2)(F) authority as a cost control measure, rather than to control what CMS determined to be an unnecessary increase

in the volume of clinic visit services provided in the excepted off-campus PBD setting. Pls.' Opp'n at 17-18. Plaintiffs are incorrect. To be sure, the concepts of volume and costs are closely related. A higher volume of services naturally leads to higher costs to the Medicare program. Similarly, as Congress recognized in Subsection (t)(9)(C), CMS may change the update to the conversion factor, which reduces payment rates, in order to address uncontrolled, unnecessary volume increases. 42 U.S.C. § 1395*l*(t)(9)(C). Here, CMS reasonably deployed a method of creating parity between the OPPS and PFS-equivalent payment rates in order to address an unnecessary increase in volume. *See* 83 Fed. Reg. 59,009. The fact that the Rule will *affect* costs does not mean that CMS acted outside of its Subsection (t)(2)(F) authority.

Plaintiffs also push back on the assertion that the volume of clinic visit services has increased unnecessarily. They point out that, as a general matter, "[t]he volume of services can increase or decrease for any number of 'necessary' reasons, such as population growth[.]" Pls.' Opp'n at 18. That's 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.* In the Rule, CMS determined based on its expertise and the available data that the increase in volume of clinic visits in the off-campus PBD setting is, in fact, unnecessary because the same services can be performed safely in the lower cost physician office setting. 83 Fed. Reg. at 59,007; *see also* Def.'s Opening Brief at 6-7 (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 increase in volume. That decision was perfectly reasonable and authorized by the statute.

Plaintiffs also suggest, oddly enough, that CMS has "studiously avoided" making a determination that the volume of clinic visit services provided by excepted off-campus PBDs has increased "unnecessarily." Pls.' Opp'n at 18. Not true. CMS made precisely that finding in the preamble to the Rule. *See, e.g.*, 83 Fed. Reg. at 59,007 ("We believe that this volume growth and the resulting increase in beneficiary cost sharing is unnecessary because it appears to have been incentivized by the difference in payment for each setting rather than patient acuity."). Thus, CMS implemented the Rule to address an unnecessary increase in the volume of clinic visit services, and the Rule is a proper exercise of CMS's Subsection (t)(2)(F) authority.

C. Congress Has Never Declared All Covered OPD Services To Be "Necessary"

Next, Plaintiffs accuse CMS of "overrrid[ing]" Congress's judgment as to which services are "necessary." Pls.' Opp'n at 16-17. But this argument is essentially a re-hash of Plaintiffs' claim that Section 603 made OPPS rates untouchable for excepted off-campus PBDs, and the argument must fail for the same reasons. *See* Part III.A, *supra*. In Section 603, Congress determined that excepted off-campus PBDs should remain in the OPPS, subject to CMS's authority to administer that system. *See* 42 U.S.C. § 1395*l*(t)(21)(A). Contrary to Plaintiffs' claims, that decision says nothing about what volume of service is appropriate for any individual service or group of services. Again, following Congress's enactment of Section 603, CMS retains the explicit authority to develop methods to control unnecessary increases in volume. *See id.* § 1395*l*(t)(2)(F). To accept Plaintiffs' view—*i.e.*, that all covered OPDs services are "necessary" by congressional decree—would read Subsection (t)(2)(F) out of the statute entirely. In other words, under Plaintiffs' reading of Section 603, CMS could never find an unnecessary increase in the volume of services.

The differences between this case and *Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009), are not difficult to follow, as Plaintiffs claim, *see* Pls.' Opp'n at 17. In *Hays*, Congress

"minutely detailed" the specific "reimbursement rates for covered items and services." 589 F.3d at 1282 (noting that the "statutory formula requires the Secretary to reimburse a particular drug at 106% pf the average sales price for drugs within its billing and payment code"); *see also* 42 U.S.C. § 1395w-3a(b)(1). Here, by contrast, despite Plaintiffs' attempts to obscure the point, Congress has not specified any specific rate that CMS must pay excepted off-campus PBDs. *See id.* § 1395*l*(t)(2)(C). And, in Section 603, Congress merely established that excepted off-campus PBD will continue to be paid through the OPPS, 42 U.S.C. § 1395*l*(t)(21)(A), while at the same time leaving it to CMS to determine how to control any unnecessary increases in the volume of services paid through that system, 42 U.S.C. § 1395*l*(t)(2)(F). Had Congress intended to codify that all covered OPD services are "necessary," it certainly would have removed CMS's explicit authority to address "unnecessary increases in the volume" of those services.

D. Nothing Requires Methods to Control Unnecessary Volume to Be Budget Neutral

Plaintiffs argue, finally, that any method developed under Subsection (t)(2)(F) must be budget neutral. *See* Pls.' Opp'n at 18-20. That is plainly incorrect, despite Plaintiffs' attempts at interpretive gymnastics. As Defendant has explained, and as the statute makes clear, the budget neutrality provision that forms the basis for Plaintiffs' argument, Subsection (t)(9)(B), applies only to adjustments made under Subsection (t)(9)(A). *See* 42 U.S.C. § 1395*l*(t)(9)(B). Yet, Subsection (t)(9)(A), as Plaintiffs concede, *see* Pls.' Opp'n at 18-19, applies only to "wage and other adjustments described in [Subsection (t)(2)]." Plaintiffs press on to claim that—because Subsection (t)(2)(F) is located within Subsection (t)(2)—any "method" CMS develops pursuant to Subsection (t)(2)(F) must necessarily be an "adjustment." *See* Pls.' Opp'n at 18-19. Plaintiffs' proffered interpretation is wrong for at least three reasons.

First, within Subsection (t)(2), Congress referred to "adjustments" in some places, *see* 42 U.S.C. § 1395*l*(t)(2)(D); *id.* § 1395*l*(t)(2)(D), and used the distinct term "method" elsewhere, *id.* § 1395*l*(t)(2)(F). It cannot be, therefore, that Subsection (t)(9)(B), which refers only to "adjustments" applies to a "method" CMS develops under Subsection (t)(2)(F). Plaintiffs try to avoid this straightforward interpretive conclusion by claiming that Subsection (t)(2)(F) and Subsection (t)(2)(E) "overlap," and that the Court should therefore apply the budget neutrality requirement in Subsection (t)(9)(A) to both. *See* Pls.' Opp'n at 19. But Plaintiffs do not explain why that should be. Again, Subsection (t)(2)(F) refers to a "method" developed to control unnecessary increases in the volume of services. Subsection (t)(2)(E), in contrast, refers to various types of adjustments, such as those "determined to be necessary to ensure equitable payments." It is those "adjustments," along with the "adjustments" described in Subsection (t)(2)(D), that must be budget neutral under Subsection (t)(9)(B)'s plain terms. Had Congress intended for Subsection (t)(9)(B) to cover methods developed under Subsection (t)(2)(F), it could have easily done so, either by explicitly referencing Subsection (t)(2)(F), or by referring to "other adjustments or methods." *Compare* 42 U.S.C. § 1395*l*(t)(2)(B) (requiring budget neutrality only for "adjustments under subparagraph (A)").

Second, Plaintiffs ignore that Subsection (t)(9)(C), which directly follows the budget neutrality provision in the statute, explicitly authorizes CMS to change the update to the conversion factor if the CMS determines "under methodologies described in [Subsection (t)(2)(f)]" that unnecessary volume increases have continued unabated. 42 U.S.C. § 1395*l*(t)(9)(C). Those changes to the conversion factor update are decidedly *not* budget neutral, and Plaintiffs do not argue otherwise. It is therefore undeniable that, in the face of an unnecessary increase in the volume of services, CMS may take steps that reduce the overall

payments made through the OPPS system, and the budget neutrality requirement in Subsection (t)(9)(B) does not apply when CMS exercises its Subsection (t)(2)(F) authority.

Finally, unlike the two subsections preceding it, Subsection (t)(2)(F) does not include a free-standing budget neutrality requirement. *Compare id.* § 1395*l*(t)(2)(F), *with*, *id.* 1395*l*(t)(2)(D), *and*, 1395*l*(t)(2)(E). As Defendant has explained, Congress has thus shown that it knows how to require budget neutrality when it wants to, and this Court should be reluctant to read into Subsection (t)(2)(F) any such requirement in the absence of express statutory language. *See* Def.'s Opening Br. at 24-25.

CMS's interpretation that a method developed under Subsection (t)(2)(F) need not be budget neutral, as Defendant has explained, is also consistent with Congress's goal of controlling public expenditures and ensuring the health of the Medicare program. Requiring budget neutrality when addressing an "unnecessary" increase in the volume of services would be nonsensical, because it would allow unnecessary services to continue to drive up costs to the Medicare program irreversibly. *See* Def.'s Opening Br. at 23.

Plaintiffs' attempt to provide a policy justification to explain why Congress would have required budget neutrality in the face of an unnecessary increase in the volume of services is feeble, and ultimately futile. They claim that Congress intended to "protect[] providers' interests in the predictability of payment and in a guarantee that OPPS payments, at least in the aggregate, will be adequate to cover the costs of providing those services." Pls.' Opp'n at 19. To accept that argument, however, the Court would need to ignore that Congress gave CMS the option in Subsection (t)(9)(C) to reduce costs in a non-budget neutral manner if a method developed under Subsection (t)(2)(F) failed to address the unnecessary increase in the volume of services. Plaintiffs acknowledge that possibility elsewhere in their brief, *see* Pls.' Mem. at 14 (discussing

the conversion factor), but then inexplicably insist that any change under Subsection (t)(2)(F) must be budget neutral when it comes to discussing policy. In any event, the statute is clear that CMS's actions need not be budget neutral when addressing an unnecessary increase in the volume of services, and Plaintiffs' arguments therefore lack merit.

IV. 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 enter an injunction ordering that CMS change its payment policies and provide immediate payments to Plaintiffs at the pre-Rule rate. *See* Second Am. Compl., Relief Requested, ECF No. 15. Plaintiffs now appear to have moved away from that request. *See* Pls.' Opp'n at 20-21. However, 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 26; *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 "because the calendar year has now begun, and given budget-neutrality constraints." Pls.' Opp'n at 20-21. But Plaintiffs do not come close to demonstrating that this case falls within the "rare circumstances" where remand is 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.

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Respectfully submitted,

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