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, United States Department of Health & Human Services, *Defendant*.	)	Case No. 1:20-CV-00075-JDB

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

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INTRODUCTION

Defendant should prevail in this litigation for the reasons discussed in his opening brief and below. Yet, this Court need not wade into the fray. On April 17, the D.C. Circuit heard argument on the precise issues presented in this litigation in Defendant's appeal of Judge Collyer's decision in *American Hospital Association v. Azar*, 410 F. Supp. 3d 142 (D.C.C. 2019) ("*AHA I*"). Defendant respectfully submits that the most prudent course would be to await the D.C. Circuit's decision on the merits, which Defendant expects to be issued in the current term and which will likely be dispositive in this litigation.

Even if the Court is inclined to address the merits now, despite the D.C. Circuit's ongoing consideration, Plaintiff has failed to show that their case is justiciable or that the Department of Health and Human Services ("HHS") acted unlawfully. In response to Defendant's motion to dismiss and cross-motion for summary judgment, Plaintiffs 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 HHS's otherwise broad authority to regulate their payment rates, forever prohibiting the agency from 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 HHS's authority to control unnecessary increases in the volume of services.

Plaintiffs also argue that, if HHS 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) ("Paragraph (t)(2)(F)"), HHS 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.

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. PLAINTIFFS' CLAIMS ARE NOT JUSTICIABLE

A. Judicial Review of Plaintiffs' Claims is Precluded.

Defendant explained in his opening brief that 42 U.S.C. § 1395*l*(t)(12)(A) precludes review of claims, like Plaintiffs', challenging HHS'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). *See* Defs.' Opp'n to Ps.' Mot. for Summ. J & Mem. in Supp. of Cross-Mot. to Dismiss or, in the Alternative, for Summ. J. at 12-14, ECF No. 14-1 ("Defs.' Mem."). Plaintiffs predictably disagree, arguing that § 1395*l*(t)(12)(A) does not apply because the agency allegedly acted outside the scope of its method-development authority. *See* Pls.' Reply in Supp. of their Mot. for Summ. J. & Mem. in Opp'n to Defs.' Mot. to Dismiss at 4-5, ECF No. 16 ("Pls.' Opp'n"). 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, HHS's action falls well within the scope of its statutory authority. Accordingly, § 1395*l*(t)(12)(A)

applies, precluding judicial review and, thereby, depriving the Court of jurisdiction over this action.

B. Plaintiffs Failed To Exhaust Administrative Remedies.

Even if 42 U.S.C. § 1395*l*(t)(12)(A) did 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 Mem. at 14-16. 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 HHS's position. Pls.' Opp'n at 5-7.

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 and therefore have not exhausted the necessary administrative remedies.

II. THE RULE IS LAWFUL AND SHOULD BE UPHELD.

A. HHS 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 HHS action that would affect the rates at which HHS pays them. *See* Pls.' Opp'n at 15-20. 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 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 HHS—after having determined that there has been an unnecessary increase in the volume of clinic visit services specifically—from exercising its separate Paragraph (t)(2)(F) authority to address that particularized concern. *See* Def.'s Mem. at 22-27.

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 HHS the authority elsewhere, in Paragraph (t)(9)(C), to adjust the conversion factor that affects payment rates for "all

covered OPD services." *See* Pls.' Opp'n at 9. "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 15-20, and how Congress intended to "preserv[e] OPPS payment rates for existing facilities," *id.* at 2—Plaintiffs have already conceded that HHS may reduce payment rates to excepted off-campus PBDs if it determines that there is an unnecessary increase in the volume of services.

Plaintiffs further assert that, if HHS exercises its Paragraph (t)(2)(F) authority, then it must do so for all services pursuant to Paragraph (t)(9)(C), rather than just for those services that it determines are unnecessary. *See* Pls.' Opp'n at 9. That is incorrect, as discussed below and in Defendant's opening brief. *See* Part II.B *infra*; Def.'s Mem. at 17-22. But the larger point is that, while Congress determined that excepted off-campus PBDs should continue to be paid under the OPPS, HHS 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, Pls.' Opp'n at 17, 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 HHS allegedly ignored Congress's concern for vulnerable populations, which Plaintiffs contend is reflected in Section 603. Pls.' Opp'n at 16-17. To be sure, Congress cares about Medicare beneficiaries, as does HHS, which promulgated the Rule and its 2019 predecessor 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); 84 Fed. Reg. 61,142, 61,369 (Nov. 12 2019). 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 of 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 16-17 (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 17 (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 HHS lawfully exercised its authority, the Court must look at the legislation Congress actually passed, which unambiguously left HHS 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 HHS of ignoring that legislation. Pls.' Opp'n at 18. 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 HHS 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 HHS's authority to control unnecessary increases in the volume of services under Paragraph (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 HHS from exercising its Paragraph (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 HHS's Paragraph (t)(2)(F) authority. But it did not. Rather, Congress left excepted PBDs subject to HHS's Paragraph (t)(2)(F) authority. Plaintiffs' arguments therefore fail.

In Section 603, Congress made a broad, generalized determination that excepted off-campus PBDs should remain within the OPPS. Thus, 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 a specific payment rate in every instance in perpetuity. Here, HHS used its Paragraph (t)(2)(F) authority, which Congress retained in Section 603, to address the narrow, 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 21. Nothing in Section 603 precludes HHS'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. HHS Properly Exercised Its Authority Under Paragraph (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 Mem. at 16-22. Plaintiffs understandably wish that HHS 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 in the more expensive off-campus PBD setting. But Plaintiffs fail to show that HHS exceeded its authority under Paragraph (t)(2)(F).

Plaintiffs again assert that HHS is not allowed to apply a method under its Paragraph (t)(2)(F) authority to any specific OPD service. *See* Pls.' Opp'n at 7-11. 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 HHS from reducing rates for any specific service, unless it also arbitrarily reduces rates for other services (by changing the conversion factor update). *See id.* But why would that be? Such a requirement would effectively prevent HHS from ever addressing an unnecessary increase in the volume of any specific service, and HHS's Paragraph (t)(2)(F) authority would serve no useful function. Under Plaintiffs' interpretation, HHS 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 HHS has found no such unnecessary increase in volume. Fortunately, Congress did not enact such an irrational statute.

Turning to the text: Paragraph (t)(2)(F) directs HHS 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 HHS's actions do not fall within the dictionary definition of what constitutes a "method." *Compare* Pls.' Mem. at 22; *see also* Def.'s Mem. at 19-20 (responding to Plaintiffs' argument). Instead, Plaintiffs raise a new argument. They assert that, because Paragraph (t)(2)(F) refers to "covered OPD services," plural, which is a defined term, *id.* at § 1395*l*(t)(1)(B), HHS may not implement a method to address an unnecessary increase in the volume of any one covered OPD service, singular. *See* Pls.' Opp'n. at 8. This hyper technical and cramped reading of the Medicare statute cannot save Plaintiffs' case. While Plaintiffs are correct that Paragraph (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, HHS 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 HHS's determination that the increase in the volume of clinic visit services specifically was unnecessary, or to its analysis of the volume of services provided by excepted off-campus PBDs overall, HHS's action is comfortably within its statutory authority either way.

Pointing to Paragraph (t)(9)(C), Plaintiffs also continue to insist that the only way HHS may control volume is through an across-the-board adjustment. *See* Pls.' Opp'n at 9. But if that's

so, Congress would not have said that HHS "*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 Mem. at 18 (citing *Dickson v. Sec'y of Def.*, 68 F.3d 1396, 1401 (D.C. Cir. 1995)). And, of course, Congress's decision to allow HHS 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 Mem. at 20-21.

Plaintiffs further accuse HHS of improperly using its Paragraph (t)(2)(F) authority as a cost control measure, rather than to control what HHS 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 13-14. 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 Paragraph (t)(9)(C), HHS 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, HHS 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 HHS acted outside of its Paragraph (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 13. 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 HHS the authority to make that determination, *id.* In the Rule, HHS 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 6-9 (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). HHS 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 HHS 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 13. Not true. HHS 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, HHS implemented the Rule to address an unnecessary increase in the volume of clinic visit services, and the Rule is a proper exercise of HHS's Paragraph (t)(2)(F) authority.

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

Next, Plaintiffs accuse HHS of "overrrid[ing]" Congress's judgment as to which services are "necessary." Pls.' Opp'n at 11-13. 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 II.A, *supra*. In Section 603, Congress determined that excepted off-campus PBDs should remain in the OPPS, subject to HHS'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, HHS 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 Paragraph (t)(2)(F) out of the statute entirely. In other words, under Plaintiffs' reading of Section 603, HHS 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 12. 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% of 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, Congress has not specified any specific rate that HHS 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 HHS 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 HHS'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 Paragraph (t)(2)(F) must be budget neutral. *See* Pls.' Opp'n at 14-15. That is incorrect. As Defendant has explained, and as the

statute makes clear, the budget neutrality provision that forms the basis for Plaintiffs' argument, Paragraph (t)(9)(B), applies only to adjustments made under Paragraph (t)(9)(A). *See* 42 U.S.C. § 1395*l*(t)(9)(B). Yet, Paragraph (t)(9)(A), as Plaintiffs concede, *see* Pls.' Opp'n at 14, applies only to "wage and other adjustments described in paragraph (t)(2)." Plaintiffs press on to claim that—because Paragraph (t)(2)(F) is located within Paragraph (t)(2)—any "method" HHS develops pursuant to Paragraph (t)(2)(F) must necessarily be an "adjustment." *See* Pls.' Opp'n at 14-15. Plaintiffs' proffered interpretation is wrong for at least three reasons.

First, within Paragraph (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 Paragraph (t)(9)(B), which refers only to "adjustments" applies to a "method" HHS develops under Paragraph (t)(2)(F). Plaintiffs try to avoid this straightforward interpretive conclusion by claiming that Paragraph (t)(2)(F) and Paragraph (t)(2)(E) "overlap," and that the Court should therefore apply the budget neutrality requirement in Paragraph (t)(9)(A) to both. *See* Pls.' Opp'n at 14. But Plaintiffs do not explain why that should be. Again, Paragraph (t)(2)(F) refers to a "method" developed to control unnecessary increases in the volume of services. Paragraph (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 Paragraph (t)(2)(D), that must be budget neutral under Paragraph (t)(9)(B)'s plain terms. Had Congress intended for Paragraph (t)(9)(B) to cover methods developed under Paragraph (t)(2)(F), it could have easily done so, either by explicitly referencing Paragraph (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 Paragraph (t)(9)(C), which directly follows the budget neutrality provision in the statute, explicitly authorizes HHS to change the update to the conversion factor if HHS determines "under methodologies described in [Paragraph (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 therefore follows that, in the face of an unnecessary increase in the volume of services, HHS may take steps that reduce the overall payments made through the OPPS system, and the budget neutrality requirement in Paragraph (t)(9)(B) does not apply when HHS exercises its Paragraph (t)(2)(F) authority.

Finally, unlike the two paragraphs preceding it, Paragraph (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 Paragraph (t)(2)(F) any such requirement in the absence of express statutory language. *See* Def.'s Mem. at 23-24.

HHS's interpretation that a method developed under Paragraph (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 Mem. at 22-23.

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

unpersuasive. 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 15. To accept that argument, however, the Court would need to ignore that Congress gave HHS the option in Paragraph (t)(9)(C) to reduce costs in a non-budget neutral manner if a method developed under Paragraph (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 9 (discussing the conversion factor), but then insist that any change under Paragraph (t)(2)(F) must be budget neutral. In any event, the statute is clear that HHS's actions need not be budget neutral when addressing an unnecessary increase in the volume of services, and Plaintiffs' arguments therefore lack merit.

III. THIS COURT SHOULD AWAIT GUIDANCE FROM THE D.C. CIRCUIT RATHER THAN GIVE PRECLUSIVE EFFECT TO *AHA I*.

Plaintiffs point to Judge Collyer's decision in *AHA I* and argue that "collateral estoppel dictates that the Plaintiff Hospitals should prevail here as well." Pls.' Opp'n at 20-21. Defendants do not dispute, of course, that Judge Collyer vacated the relevant portion of the 2019 Rule. However, Plaintiffs' argument that the Court should give preclusive effect to the *AHA I* decision largely ignores Defendants' appeal of that decision to the D.C. Circuit. Defendant requested and obtained an expedited briefing schedule to allow the D.C. Circuit to decide the case in its current term, and oral argument took place on April 17. In this circumstance, where the appeal is proceeding "with reasonable dispatch," Defendant respectfully submits that the most prudent course would be to "defer consideration of the preclusion question until the appellate proceedings addressed in the prior judgment are concluded." *Martin v. Malhoyt*, 830 F.2d 237, 265 (D.C. Cir. 1987); *see also id.* at 264 ("[C]are should be taken in dealing with judgments that are final, but

still subject to direct review."). The D.C. Circuit is currently considering the precise questions at issue in this case, and its decision will be dispositive in all likelihood.

It is also worth noting that, even if the Court were to agree with Plaintiffs that Defendant is estopped from enforcing the Rule as to the named Plaintiffs who participated in *University of Kansas Hospital Association v. Azar*, No. 1:19-cv-132-RMC (D.D.C.), and *Hackensack Meridian Health v. Azar*, No. 1:19-cv-1745-RMC (D.D.C.), which were consolidated with *AHA I*, there are additional named Plaintiffs in this case that were not a party to that litigation. *See* Pls.' Mem. in Support of Mot. for Summ. J. at 31 n.5, ECF No. 11-1. Thus, under the doctrine of collateral estoppel, the Court would still need to reach the merits in order to resolve the claims of the remaining named Plaintiffs. *See Johnson v. United States*, 841 F. Supp. 2d 218, 220 (D.D.C. 2012) ("Under the doctrine of collateral estoppel, or issue preclusion, an issue of fact or law that was actually litigated and necessarily decided is conclusive in a subsequent action *between the same parties or their privies.*" (emphasis added)); *Am. Fed'n of Gov't Employees. v. Federal Labor Relations Authority*, 835 F.2d 1458, 1462 (D.C. Cir. 1987) (collateral estoppel applies against the government only where mutuality of parties exists). This complication—that estoppel would apply only to some of the named Plaintiffs in this lawsuit—further weighs in favor of awaiting guidance from the D.C. Circuit.

IV. IF PLAINTIFFS PREVAIL, REMAND IS THE APPROPRIATE REMEDY

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 HHS change its payment policies and provide immediate payments to Plaintiffs at the pre-Rule rate. *See* Am. Compl., Relief Requested, ECF No. 10. Plaintiffs now appear to have moved away from that

request. *See* Pls.' Opp'n at 23. However, to the extent Plaintiffs still envision the Court ordering specific payments or directing HHS to take some specific regulatory action on remand, the Court is not authorized to provide that relief. *See* Def.'s Mem. at 28-29; *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 HHS'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 deny Plaintiffs' motion for summary judgment and grant Defendant's motion to dismiss or, in the alternative, for summary judgment. However, to the degree the Court has any doubt, Defendant respectfully asks that the Court stay a decision on the parties' motions pending resolution of Defendant's appeal to the D.C. Circuit in *AHA I*.

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Respectfully submitted,

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