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

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INTRODUCTION

The Plaintiff hospitals have for years enjoyed a payment policy that has allowed them to operate off-campus facilities as hospital outpatient departments (OPDs), and to be paid at hospital outpatient rates. This policy created a financial incentive for hospitals to open more off-campus OPDs, or purchase freestanding physician practices and convert the billing from the Physician Fee Schedule to the higher-paying hospital Outpatient Prospective Payment System (OPPS). While Congress intervened to halt the proliferation of new off-campus OPDs in 2015, it did not address once and for all the problem of Medicare having to pay significantly more for certain services, like clinic visits, that could be just as easily, and safely, performed in a physician office and be paid for at a lower rate, nor did Congress purport to. The payment disparity creates a perverse incentive to increase utilization of clinic visits furnished in off-campus OPDs.

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

Plaintiffs' suit fails at the outset because this Court lacks jurisdiction to hear it. The Medicare statute expressly precludes judicial review of claims challenging the Secretary's exercise of his method-development authority under paragraph (2)(f), 42 U.S.C. § 1395*l*(t)(2)(F), and Plaintiffs have not exhausted their administrative remedies. Plaintiffs attempt to avoid the first of these jurisdictional defects by arguing that HHS's action was *ultra vires*. But Plaintiffs cannot show that HHS clearly exceeded its regulatory jurisdiction, as required to invoke the *ultra vires*

exception to preclusion. To the contrary, HHS acted well within its statutory authority, and therefore Plaintiffs' claims fail.

In support of their *ultra vires* claim, Plaintiffs contend that HHS did not, in fact, employ a "method" under paragraph (2)(F). Plaintiffs are wrong. Plaintiffs narrowly read the Medicare statute to authorize HHS action only if it is an across-the-board reduction in Medicare payments. But the statute does not require HHS to deploy such draconian measures to address what it identifies as an "unnecessary increase[] in the volume" of an isolated type of service. And why would it? If the Secretary has determined there is an unnecessary increase in the volume of a covered OPD service, it is only natural Congress would want HHS to act only with respect to that specific service. And, as discussed below, the language and structure of the Medicare statute supports that common-sense reading.

Plaintiffs also argue that the Rule is invalid because it is not budget neutral. But the statutory provision that underpins the Rule, paragraph (2)(F), contains nary a mention of budget neutrality, and Congress was not shy elsewhere in the Medicare statute about explicitly requiring budget neutrality when it was intended. And, here again, it would make little sense for Congress to require budget neutrality when HHS is acting to address an *unnecessary* increase in the volume of services. Otherwise, HHS actions would only create a windfall to other providers, because, if Plaintiffs' theory were correct, HHS would need to overcompensate them to offset any reduction implemented to address unnecessary volume increases.

Plaintiffs further claim that the Rule is unlawful because it sets payment rates for a limited subset of services provided by OPDs at the same rate Medicare would pay for those services if they were provided at a physicians' office. Plaintiffs rely on a 2015 statute in which Congress tried to slow the runaway increase in the provision of OPD services by prohibiting certain off-campus

provider-based departments (so-called "off-campus PBDs"[1]) of a hospital that were not billing under the higher outpatient fee schedule applicable to such departments as of November 1, 2015 from doing so after that date. It allowed off-campus PBDs billing under the higher fee schedule as of November 1, 2015 to continue doing so. Plaintiffs infer from this action that Congress wanted to leave forever untouched off-campus PBDs already billing under the higher fee schedule, no matter what may come. Plaintiffs' inference is untenable. Nothing in the statute prevents HHS—having determined that there has been an unnecessary increase in the volume of clinic visit services among providers who continue to bill under the higher fee schedule—from exercising its statutory authority to otherwise control increases in the volume of those services. And, indeed, Plaintiffs' interpretation would effectively read out of the Medicare statute HHS's authority to control unnecessary increases in service volume altogether. Congress's concern about the volume of OPD services, coupled with its broad delegation of authority to the agency to operate the Medicare system, only underscores that the Rule is fully in line with congressional intent.

Plaintiffs argue, finally, that HHS is collaterally estopped from applying the second phase of the method to the Plaintiff hospitals. *See* Pls.' Mem. in Supp. of Pls.' Mot. for Summ. J (Pls.' Mem.) at 31-32, ECF No. 11-1. Plaintiffs are again incorrect. Defendant recognizes that another Court in this District has concluded that HHS's development of the same method in the OPPS rule governing the 2019 calendar year, 83 Fed. Reg. 58,818 (Nov. 21, 2018) (2019 Rule), was unlawful and therefore vacated the relevant portion of the 2019 Rule, *see Am. Hosp. Ass'n v. Azar*, 410 F.

[1] "PBD" stands for "provider-based department." For the purposes of Defendant's opposition, "PBD" and "OPD" are effectively interchangeable, except that the Rule applies only to the more limited set of facilities that fall within the specific definition of "off-campus PBDs," which are those OPDs that do not offer services at the physical campus of the hospital with which they are associated, or within a specific distance from a remote location of a hospital facility. *See* 42 C.F.R. § 413.65(a)(2). For technical clarity, Defendant uses the term "off-campus PBD" as appropriate.

Supp. 3d 142, 160-61 (D.D.C. 2019); *Am. Hosp. Ass'n v. Azar*, Civ. A. No. 18-2841 (RMC), 2019 WL 5328814, at *3 (D.D.C. Oct. 21, 2019) (*AHA I*). However, HHS has appealed that decision to the D.C. Circuit, and there is significant uncertainty whether it will be upheld. This Court should therefore decline to give preclusive effect to that decision. But even if the Court were inclined to agree with Plaintiffs' preclusion argument, the most prudent course would be to stay consideration of the parties' motions pending Defendant's appeal. The same legal issues presented by this suit are pending before the D.C. Circuit, which will hear oral argument on April 17. That appeal was expedited to allow the D.C. Circuit to issue a decision by the end of its current Term.

STATUTORY AND REGULATORY BACKGROUND

Title XVIII of the Social Security Act of 1935, as amended, commonly known as the "Medicare Act," 42 U.S.C. §§ 1395 *et seq.*, establishes a federally funded insurance program for the elderly and disabled. Part B of Medicare is a voluntary program that provides supplemental coverage for certain kinds of care, including for services furnished by OPDs.

A. The Outpatient Prospective Payment System

HHS pays for OPD services under the OPPS. By contrast, most inpatient hospital services are paid under a separate payment system. Under the OPPS, HHS makes payments according to predetermined rates set yearly and paid directly to providers. For covered OPD services, the Secretary must develop a classification system for individual services or groups of related services. 42 U.S.C. § 1395*l*(t)(2)(A)-(B). In implementing this system, the Secretary grouped hospital outpatient services into classifications called Ambulatory Payment Classifications (APCs). 42 C.F.R. § 419.31. APCs, in part, encompass services that are clinically similar and require similar resources.

For each such service or group of services, the Secretary may establish relative payment weights based on historical data regarding the median or mean cost of the service(s) within the APC. *See* 42 U.S.C. § 13951(t)(2)(C). The amount of the OPPS payment to a hospital for a particular service is established in part by multiplying the "conversion factor"—the base amount used to determine payments for all services under OPPS—by the APC relative weight. 42 U.S.C. § 1395*l*(t)(3)(C)-(D). A percentage of this figure is paid by the beneficiary as a co-pay, and the remainder of the OPPS payment rate for that APC is paid by Medicare. *See* 42 U.S.C. § 1395*l*(t)(8).

The Medicare Act authorizes the Secretary to modify OPPS payments for various reasons. *See* 42 U.S.C. § 1395*l*(t)(2). Congress was clear that, when the Secretary makes payment changes for certain reasons, the payment changes must be budget neutral (*i.e.*, not affect the total amount spent through the OPPS for the calendar year). Those changes that require budget neutrality include wage adjustments to reflect differences in the cost of labor, outlier adjustments for cases with unusually high costs, transitional pass-through payments for certain innovative drugs, biologicals, and devices, and "other adjustments as determined to be necessary to ensure equitable payments." 42 U.S.C. § 1395*l*(t)(2)(D), (E). Similarly, Congress required budget neutrality when the Secretary adjusts payments to consider "changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors." *Id.* § 1395*l*(t)(9)(A). To comply with these budget neutrality requirements, when the Secretary makes payment adjustments for any of these reasons, he must make offsetting increases or decreases to the payment rates for other covered services. *See id.* § 1395*l*(t)(2)(D), (E); 1395*l*(t)(9)(B).

Congress also gave the Secretary the authority to take other steps specifically to control the volume of services—and, by extension, the cost of the OPPS. Under paragraph (2)(F), the Secretary "shall develop a method for controlling unnecessary increases in the volume of covered

OPD services." *Id.* § 1395*l*(t)(2)(F). That provision, unlike those discussed above, lacks a budget-neutrality requirement. *Id.*

B. Extraordinary Growth in the Volume of OPD Clinic Visit Services.

Since Congress implemented the OPPS in 1997, OPD services have been the fastest growing sector of Medicare payments in all payment systems across Medicare Parts A and B, raising serious concerns that the rate of growth is due to the higher payment rates provided for OPD services compared to those provided for services performed in physician offices. As a general matter, the payment rates for OPD services under the OPPS are higher than the payment rates for the same or similar services provided in freestanding physician offices, dramatically increasing costs to both Medicare and beneficiaries. The Medicare Payment Advisory Commission (MedPAC)—an independent congressional agency established to advise Congress on issues affecting the Medicare Program, *see* 42 U.S.C. § 1395b-6(a)—concluded in its March 2017 report to Congress that, from 2005 to 2015, the volume of OPD services per beneficiary grew by 47 percent. *See Report to the Congress, Medicare Payment Policy* at 69, MedPAC (Mar. 2017), http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf (MedPAC March 2017 Report).[2]

A substantial portion of this remarkable growth was due to an increase in the number of evaluation and management visits billed as outpatient clinic visit services.[3] From 2012 to 2015, OPD clinic visit services per beneficiary grew by 22 percent, compared with a 1 percent *decline* in physician office-based visits. *See* MedPAC March 2017 Report at 70; *see also* 83 Fed. Reg. at 59,006. MedPAC has documented how this growth is due in part to hospitals purchasing

[2] MedPAC submits reports to Congress twice per year, once in March and once in June. 42 U.S.C. § 1395b-6(b)(1).

[3] Clinic visit services are those billed to Medicare under a specific Healthcare Common Procedure Coding System code G0463. That code is valid for a "hospital outpatient clinic visit for assessment and management of a patient."

freestanding physician practices and converting these facilities to PBDs in order to bill for services under the higher paying OPPS rather than the Medicare Physician Fee Schedule (PFS). MedPAC March 2017 Report at 70; *see also Report to the Congress, Medicare Payment Policy* at 73, MedPAC (Mar. 2018), http://www.medpac.gov/docs/default-source/reports/mar18_medpac_entirereport_sec.pdf (MedPAC March 2018 Report); 83 Fed. Reg. at 59,006.

The financial incentive for providers to furnish clinic visit services in an OPD rather than a physician office is significant. In 2019, the standard unadjusted Medicare OPPS proposed payment for a clinic visit is approximately $116, with an average co-pay from the beneficiary of $23. By contrast, the proposed PFS rate for a clinic visit is approximately $46, with a copay of around $9. *See* 83 Fed. Reg. at 59,009. Based on this significant disparity, and the resulting costs to both the federal government and beneficiaries, MedPAC has repeatedly questioned the appropriateness of higher payment rates to OPDs compared to physician offices, and has recommended that the disparity be reduced or eliminated for services that can be provided safely in a non-hospital setting. *See* MedPAC March 2018 Report at 73 (reiterating MedPAC's recommendations from prior reports).[4]

[4] Other observers have similarly documented the payment disparity between the OPPS and PFS systems, which results in more procedures performed in the OPD setting and higher costs to beneficiaries and the public fisc. *See, e.g.*, Avalere Health, *Medicare Payment Differentials Across Outpatient Settings of Care* (Feb. 2016), http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/Payment-Differentials-Across-Settings.pdf; Physicians Advocacy Institute, *Physician Practice Acquisition Study: National Regional Employment Changes* (Sept. 2016), http://www.physiciansadvocacyinstitute.org/Portals/0/assets/docs/PAI-Physician-Employment-Study.pdf; The Moran Company, *Cost Differences in Cancer Care Across Settings* (Aug. 2013), https://media.gractions.com/E5820F8C11F80915AE699A1BD4FA0948B6285786/adebd67d-dcb6-46e0-afc3-7f410de24657.pdf; Berkeley Research Group, *Impact on Medicare Payments of Shift in Site of Care for Chemotherapy Administration* (June 2014), https://www.thinkbrg.com/media/publication/454_Site_of__Care_Chemotherapy.pdf.

In 2015, Congress took steps to address the payment incentive for hospitals to acquire physician offices and convert them to PBDs of the hospital. In Section 603 of the Bipartisan Budget Act of 2015 (Section 603), Pub. L. No. 114-74, 129 Stat. 584, 5498 (2015), Congress amended the definition of "covered OPD services" such that services provided at off-campus hospital outpatient department locations would continue to be paid under the OPPS if those department locations—so-called "excepted off-campus PBDs"—were already billing under the OPPS as of November 1, 2015. *See* 42 U.S.C. § 1395*l*(t)(21)(B)(ii). The off-campus PBDs of a hospital that were not billing under the OPPS as of November 1, 2015—so-called "non-excepted off-campus PBDs"—would no longer provide "covered OPD services," subject to certain exceptions, and therefore would not receive payment for their services under the OPPS. *Id.*

Despite the changes to the OPPS statute made by Section 603, the unchecked growth in the utilization of clinic visit services provided in the OPD setting has continued. *See* Medicare Program; Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 83 Fed. Reg. 37,046, 37,139, Table 31 (July 31, 2018). For the 2019 calendar year, HHS estimated that, without any further steps to control utilization, the volume of OPD services would grow by 5.4 percent over the previous year, leading to total OPPS expenditures of $74.5 billion. *See* 83 Fed. Reg. at 59,012. The growth in the volume of clinic visit services specifically is an important driver of that growth. According to MedPAC's March 2018 Report, from 2011 through 2016, the volume of clinic visits rose substantially in the OPD setting, while there was only a slight growth in the volume of those services in freestanding physician offices. *See* MedPAC March 2018 Report at 73. Specifically, clinic visits to OPDs increased by 43.8 percent (or an average of 7.5 percent per year). *Id.* Over the same period, "the volume of office visits in freestanding [physician] offices rose by only 0.4

percent . . . .” *Id.* According to MedPAC, the Medicare program spent $1.8 billion more in 2016 than it would have if payment rates for clinic visits in OPDs were the same as for freestanding physician office rates. *Id.*

C. The 2019 Rule and Surrounding Litigation

To address the persistent and unnecessary increases in the volume of clinic visit services provided at excepted off-campus PBDs, HHS sought notice and comment on a 2019 proposal to use its authority under paragraph (2)(F) to pay for outpatient clinic visit services provided at those locations at the same rate that HHS uses to pay non-excepted off-campus PBDs for those same services under the separate PFS. *See* 83 Fed. Reg. at 37,142. After reviewing the public comments submitted in response to the proposal, HHS adopted the proposal with minor alterations and published the 2019 Rule in the Federal Register on November 21, 2018. *See generally* 83 Fed. Reg. at 59,013.

In the 2019 Rule, HHS detailed the continuing unrestrained growth in off-campus PBD clinic visit services and explained that it resulted in significant cost increases to the Medicare program and beneficiaries. In HHS’s judgment, the growing volume is unnecessary because it appears to be caused largely by the difference in payment rates based on where a service is provided, and the financial incentive created by the higher payment for OPD services under the OPPS, rather than on any patient need. *See id.* at 59,007; *see also id.* at 59,008 (“To the extent that similar services can be safely provided in more than one setting, we do not believe it is prudent for the Medicare program to pay more for these services in one setting than another.”). As explained in the 2019 Rule, HHS believes that “capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed.” *Id.* at 58,009. HHS

indicated that it will phase in this method for controlling the unnecessary increases in the volume of clinic visit services over two years. *Id.* at 59,914. HHS estimated that, in 2019 alone, its method would result in savings of approximately $300 million to Medicare and approximately $80 million to Medicare beneficiaries in the form of reduced copayments. *Id.*

A number of hospitals, including many of the Plaintiff hospitals in this case, brought suit against Defendant to challenge the relevant portion of the 2019 Rule. *See, e.g.*, *AHA I*, 2019 WL 5328814 (D.D.C.); *Univ. of Kansas Hosp. Auth. v. Azar*, 1:19-cv-00132-RMC (D.D.C.) (*Kansas I*). On September 17, 2019, Judge Collyer issued an opinion that declared the challenged aspect of the 2019 Rule *ultra vires*, and vacated the portion of the 2019 Rule in which HHS exercised its paragraph (2)(F) authority. *AHA I*, 410 F. Supp. 3d 142 (D.D.C.). The accompanying order directed the parties to file a joint status report discussing whether additional briefing on remedies was necessary. *See AHA I*, ECF No. 32. On October 21, 2019, the district court denied the government's motion to reconsider the remedy, *AHA I*, 2019 WL 5328814 (D.D.C.), and issued a final appealable order, *AHA I*, ECF No. 39. The government filed a timely notice of appeal in each of the consolidated cases on December 12, 2019. Briefing in Defendant's appeal is complete, and the D.C. Circuit is scheduled to hear oral argument on April 17, 2020.

D. The Challenged 2020 Rule

On August 9, 2019, before Judge Collyer ruled on the parties' cross motions for summary judgment in *AHA I* and *Kansas I*, HHS issued a notice of proposed rulemaking as part of its annual rate setting process to establish OPPS rates for the 2020 calendar year. *See* 84 Fed. Reg. 39,398. After considering comments on the proposed rule, HHS made the final version of the 2020 Rule available on its website on November 1, 2019, *see* CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-

1717-FC) (Nov. 1, 2019), https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicareprogram-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center (2020 OPPS Rule). HHS published the 2020 Rule in the Federal Register on November 12, 2019. *See* 84 Fed. Reg. 61,142.

In the preamble to the 2020 Rule, HHS acknowledged that Judge Collyer vacated its volume control method in the 2019 Rule and explained that HHS is "working to ensure affected 2019 claims for clinic visits are paid consistent with the court's order." *Id.* at 61,368. As HHS further explained, however, HHS continues to

> believe that Section 1833(t)(2)(F) of the Act grants the Secretary the authority to develop a method for controlling unnecessary increases in the volume of covered OPD services, including a method that controls unnecessary volume increases by removing a payment differential that is driving a site-of-service decision, and, as a result, is unnecessarily increasing service volume.

Id. at 61,367-68. Because HHS appealed Judge Collyer's judgment, which applies only to 2019 OPPS rates, HHS determined that it would be appropriate to implement the second phase of its volume control methodology in the 2020 Rule, which applies only to the 2020 calendar year. *Id.* at 61,368.

E. This Litigation

On March 17, 2019, Plaintiffs filed their amended complaint in this action against the Secretary of Health and Human Services in his official capacity. Am. Compl., ECF No. 10. Plaintiffs assert that they have each been paid for services at payment rates affected by the 2020 Rule and have each presented claims to Defendant seeking additional reimbursement at the pre–2020 Rule rate. *Id.* ¶ 21. Plaintiffs also allege that further administrative review of Plaintiffs' claims would be futile. *Id.*

Plaintiffs assert that the 2020 Rule is contrary to the Medicare Act, including the distinction between excepted and non-excepted PBDs that Congress created in Section 603, and that

Defendant acted unlawfully by not implementing the Rule in a "budget neutral" manner. *See id.* ¶¶ 47-53, 54-59. Plaintiffs seek declaratory and injunctive relief (i) declaring that the challenged portion of the 2020 Rule exceeds HHS's statutory authority; (ii) vacating the challenged portion of the 2020 Rule; (iii) enjoining HHS from enforcing or implementing the challenged portion of the 2020 Rule; and (iv) requiring HHS to pay legal fees and costs. *See id.*, Relief Requested. On March 17, 2019, Plaintiffs moved for summary judgment. *See* Pls.' Mem.

ARGUMENT

I. THE COURT LACKS JURISDICTION OVER PLAINTIFFS' CLAIMS

A. Judicial Review of Plaintiffs' Claims is Precluded

Although the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action," the "APA does not apply . . . 'to the extent that . . . statutes preclude judicial review.'" *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (quoting 5 U.S.C. § 701(a)). To determine "[w]hether and to what extent a particular statute precludes judicial review," a court must look to the statute's "express language, . . . the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

The Medicare statute expressly precludes judicial review of Plaintiffs' claims challenging the Secretary's exercise of his method-development authority under § 1395*l*(t)(2)(F). Specifically, 42 U.S.C. § 1395*l*(t)(12)(A) precludes review of claims, like this one, challenging the Secretary's exercise of his authority under 42 U.S.C. § 1395*l*(t)(2)(F) to "develop a method for controlling unnecessary increases in the volume of covered OPD services":

> There shall be *no* administrative or *judicial review* under section 1395ff of this title, 1395oo of this title, or otherwise of—

> (A) the *development* of the [OPPS] classification system under paragraph (2), including the establishment *of* groups and relative payment weights for covered OPD services, of wage adjustment factors, other adjustments, and *methods described in paragraph* (2)(F) . . . .

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). In the challenged Rule, the Secretary exercised precisely the method-development authority referred to above in 42 U.S.C. § 1395*l*(t)(12)(A). *See, e.g.*, 83 Fed. Reg. at 59,011 ("Further, we believe that capping the OPPS payment at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed."). Thus, the express language of the statute demonstrates that Plaintiffs' claims are precluded. And the legislative history confirms that Congress intended for § 1395*l*(t)(12) to broadly preclude judicial review—under the Medicare statute "or otherwise"—of the Secretary's development of methods for controlling unnecessary increases in the volume of outpatient services. *See* H.R. Rep. No. 105-149 at 724 (1997) ("The provision would prohibit administrative or judicial review of the prospective payment system.").

In *Amgen, Inc. v. Smith*, 357 F.3d 103 (D.C. Cir. 2004), the D.C. Circuit construed § 1395*l*(t)(12), and concluded that Congress's intention to preclude review under that provision was "'*clear and convincing*' *from the plain text of § (t)(12) alone*." *Id.* at 112 (emphasis added). That case involved the Agency's adjustment of the payment rate for an anemia treatment. *Id.* at 103. The court found "unsurprising" Congress's preclusion of review, given that "piecemeal review of individual payment determinations could frustrate the efficient operation of the complex prospective payment system." *Id.* Review of the development of a method to control unnecessary increases in the volume of OPD services could similarly frustrate the operation of the Medicare system, especially given the size of the program: The agency will likely process well over 100

million claims under the 2020 Rule. *See, e.g.*, 2016 CMS Statistics, at 42, Table V.6 (outpatient hospital claims represent 59.7 percent of 214.1 million total claims received), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Statistics-Reference-Booklet/Downloads/2016_CMS_Stats.pdf.

Plaintiffs attempt to avoid the straightforward conclusion that § 1395*l*(t)(12)(A) precludes review of their claims by invoking the *ultra vires* exception to preclusion. *See* Am. Compl. ¶ 9; Pls.' Mem. at 27. But "[t]hat argument stretches the definition of *ultra vires* action too far. An agency only acts *ultra vires* when it exceeds a clear and mandatory limit on its regulatory jurisdiction." *Baxter Healthcare Corp. v. Weeks*, 643 F. Supp. 2d 111, 115 n.2 (D.D.C. 2009); *see also Indep. Cosmetic Mfrs. & Distributors, Inc. v. U. S. Dep't of Health, Ed. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978) (a party urging jurisdiction based on *ultra vires* action must show a patent violation of agency authority); *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 522 (D.C. Cir. 2016) (holding that agency action is *ultra vires* only if it is a "patent violation of agency authority" and that "[a] violation is patent if it is obvious or apparent") (quotations marks and brackets omitted from parenthetical). No such clear limit is implicated here, as demonstrated more fully below. *See infra* Part II. This is simply "a routine 'dispute over statutory interpretation' that does not rise to the level of an *ultra vires* claim." *Baxter Healthcare Corp.*, 643 F. Supp. 2d at 115 n.2 (citing *Dart v. United States*, 848 F.2d 217, 231 (D.C. Cir. 1988)).

B. Plaintiffs Failed To Exhaust Administrative Remedies Under The Medicare Statute.

The Court lacks jurisdiction for an additional reason: Plaintiffs have not exhausted their administrative remedies as required by 42 U.S.C. § 405(g). *See Tataranowicz v. Sullivan*, 959 F.2d 268, 272 (D.C. Cir. 1992). Courts may excuse the exhaustion requirement, but "only under

rather limited conditions." *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992). As the Supreme Court has explained, 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). Thus, Plaintiffs' contention that administrative review would be futile, Am. Compl. ¶ 21, does not excuse compliance with the exhaustion requirement. *Shalala v. Ill. Council on Long Term Care, Inc.* ("*Illinois Council*"), 529 U.S. 1, 23 (2000). "The 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." *Id.*

Importantly, Congress provided a "special review route," *Illinois Council*, 529 U.S. at 23, in Section 1395*ff*(b), which sets out an abbreviated administrative review process that establishes a path to expedited judicial review 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 [] there is no material issue of fact in dispute." 42 U.S.C. § 1395*ff*(b)(2)(A).[5] But Plaintiffs have not availed themselves of this path. Plaintiffs are not entitled to forgo administrative review and go straight to court merely because they wish to "resolve [a] statutory or constitutional contention that the agency . . . cannot[] decide." *Illinois Council*, 529 U.S. at 23

[5] Section 1395*ff*(b) provides that "[t]he Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A of this chapter or enrolled under part B of this subchapter, or both, who has filed an appeal . . . may obtain access to judicial review when a review entity . . . , on its own motion or at the request of the appellant, determines that the Departmental Appeals Board 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); *see also* 42 C.F.R. § 405.990 (expedited access to judicial review). Once that determination has been made, or if it is not made within 60 days after receipt of the request, "the appellant may bring a civil action" in district court either in the judicial district in which the appellant is located or in the District Court for the District of Columbia. *Id.* § 1395*ff*(b)(2)(C).

(holding that Section 405(g) and Section 1395*ii* preclude federal question jurisdiction). So long as litigants can channel their "action" through the agency, a court may later consider "any statutory . . . contention that the agency . . . cannot[] decide." *Id.* (citing *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 215 & n. 20 (1994); *Heckler v. Ringer*, 466 U.S. 602, 617 (1984); *Salfi*, 422 U.S. at 762).

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

Plaintiffs contend that the agency misinterpreted the Medicare statute and that, in doing so, HHS will deprive hospitals of millions of dollars in Medicare payments. Am. Compl. ¶¶ 74-75. As discussed above, however, the Medicare statute precludes judicial review of a challenge, like Plaintiffs', to the Secretary's development of a method under paragraph (2)(F). 42 U.S.C. § 1395*l*(t)(12)(A). Here, Plaintiffs' *ultra vires* claim fails because the challenged portion of the 2020 Rule rests well within the agency's authority, as explained below.

Alternatively, even if Plaintiffs could meet the prerequisites for *ultra vires* review, Plaintiffs' arguments would fail under the familiar *Chevron* framework. It is well settled that HHS's interpretation of the Medicare statute is entitled to *Chevron* deference. *See, e.g.*, *Baystate Franklin Med. Ctr. v. Azar*, 950 F.3d 84, 91-92 (D.C. Cir. 2020); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417-20 (1993). The *Chevron* framework is based on the presumption "'that Congress, when it left ambiguity in a statute' administered by an agency, 'understood that the ambiguity would be resolved, first and foremost, by the agency, and desired the agency (rather than the courts) to possess whatever degree of discretion the ambiguity allows.'" *City of Arlington v. FCC*, 569 U.S. 290, 296 (2013) (citation omitted).

Chevron deference applies anytime an agency exercises its delegated authority to fill gaps in a statute. *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 173 (2007) ("[T]he

ultimate question is whether Congress would have intended, and expected, courts to treat an agency's rule, regulation, application of a statute, or other agency action as within, or outside, its delegation to the agency of 'gap-filling' authority"). Such deference is especially warranted 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 extreme complexity of the statute. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417-20 & n.13 (1993). The upshot of the *Chevron* analysis is that a court must defer to the agency's interpretation of ambiguous statutory language as long as that interpretation is reasonable. *See Judulang v. Holder*, 565 U.S. 42, 52 n.7 (2011).

A. HHS Properly Developed a Method to Control for an Unnecessary Increase in the Volume of Specific Services

In the Rule, HHS complied with Congress's directive to develop a method to control unnecessary increases in the volume of OPD services paid through the OPPS. *See* 42 U.S.C. § 1395*l*(t)(2)(F) ("[T]he Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services[.]"). Plaintiffs contend that HHS acted unlawfully, because, according to Plaintiffs, (1) HHS did not, in fact, employ a "method," which Plaintiffs contend can "play[] no role" in determining payment rates, Pls.' Mem. at 20-23; (2) Congress has deemed all of the services at issue "necessary," *see id.* at 23-25; and (3) HHS did not find an unnecessary increase in the volume of those services, *id.* at 25-26. But Plaintiffs misread the Medicare Act and the Rule and selectively cite statutory provisions in an attempt to limit the Secretary's authority under paragraph (2)(F), where no such limitation exists.

1. Plaintiffs contend that a "method" under paragraph (2)(F) "does not include the power to alter payment rates for particular services." Pls.' Mem. at 20. According to Plaintiffs, the

only way HHS may change payment rates pursuant to its paragraph (t)(2)(F) authority would be to "undertake system-wide, generally-applicable modifications to the OPPS system." *Id.* at 21.

But Plaintiffs' reading of the statute would lead to absurd results that Congress plainly did not intend. Plaintiffs provide no logical reason why Congress would have wanted HHS to take the draconian and illogical step of penalizing everyone in the OPPS system—by reducing rates for every type of OPD service—in order to control an unnecessary increase in the volume of a single, specific type of service. Rather, much more sensibly, HHS interprets paragraph (2)(F) to allow it to develop a method to control *unnecessary* increases in volume for a specific service, which can include equalizing payment rates for similar services provided at different equally safe locations.

Unsurprisingly, the language and structure of the Medicare statute support HHS's interpretation of its authority. Paragraph (9)(C) states that the Secretary "*may* appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year" if "the Secretary determines under methodologies described in [paragraph (2)(F)] that the volume of services paid for under this subsection increased beyond amounts established through those methodologies." 42 U.S.C. § 1395*l*(t)(9)(C) (emphasis added). The language Congress used—that HHS "may" adjust the conversion factor—is entirely permissive and, contrary to Plaintiffs' claim, does not tie HHS's hands to any particular course of action to control unnecessary increases in the volume of OPD services. *See Dickson v. Sec'y of Defense*, 68 F.3d 1396, 1401 (D.C. Cir. 1995) ("When a statute uses a permissive term such as 'may' rather than a mandatory term such as 'shall,' this choice of language suggests that Congress intends to confer some discretion on the agency, and that courts should accordingly show *deference* to the agency's determination"); *Adirondack Medical Ctr. v. Sebelius*, 740 F.3d 692, 697-98 (D.C. Cir. 2014) (explaining that "Congress generally knows how to use the word 'only' when drafting laws," and that specifying what the Secretary "may" do was

more likely Congress's attempt "to clarify what might be doubtful,]" rather than to impose a restriction). Indeed, the permissive nature of HHS's authority under paragraph (9)(C) stands in stark contrast with the clear directive in paragraph (2)(F) that HHS "shall" control unnecessary volume increases by developing a methodology to control them, further suggesting that HHS has options other than a conversion factor adjustment to implement a methodology (*e.g.*, by reducing payment rates, as HHS did in the Rule).

Plaintiffs point to what they call the "common-sense meaning" of paragraph (2)(F) to argue that HHS may implement that paragraph only through across-the-board cuts. Pls.' Mem. at 22. But, in fact, as discussed above, common sense strongly supports upholding the Rule, as does the language of the statute. "Method" is not defined in the Medicare Act, and HHS reasonably interprets that term to include creating parity between the OPPS and PFS-equivalent payment rates in order to address an unnecessary increase in volume. *See* 83 Fed. Reg. at 59,009. And, despite Plaintiffs' argument to the contrary, the dictionary definitions of "method" are entirely consistent with HHS's interpretation. Black's Law Dictionary, which Plaintiffs cite, defines "method" as a "mode of organizing, operating, or performing something, esp[ecially] to achieve a goal." Pls.' Mem. at 22 (quoting Black's Law Dictionary at 1141 (10th ed. 2014)). Here, HHS changed the payment structure for clinic visits provided at off-campus PBDs to achieve parity with the rates used by physician offices, to achieve the statutory goal of controlling an unnecessary increase in the volume of clinic visits at off-campus PBDs. Similarly, HHS's action is a "systematic procedure" or a "systematic plan" in that it was implemented to apply *systematically* to all clinic visit services billed under the relevant billing code. *See* Pls.' Mem. at 22 (citing Merriam-Webster Online, which includes "a systematic procedure" or "a systematic plan" in its examples of what constitutes a "method"). It is also a "way, technique, or process of or for doing something"—*i.e.*,

implementation of payment parity for certain services is a way of controlling an unnecessary increase in volume of those services. *See* Merriam-Webster Online, *Method*, https://www.merriam-webster.com/dictionary/method. Thus, HHS's action in the 2020 Rule falls comfortably within the meaning of "method."

2. In an attempt to sidestep paragraph (2)(F), Plaintiffs also advance the extraordinary argument that, in Section 603, Congress determined that *all* services provided in an excepted off-campus PBD are "necessary"—and therefore not subject to HHS's paragraph (2)(F) authority. Pls.' Mem. at 23 ("Congress found that E/M services performed by excepted off-campus hospital departments were necessary when it enacted Section 603 and specifically decided to preserve OPPS payment rates for those services[.]"); *id.* at 25 ("Congress found the volume of E/M services performed in excepted hospital outpatient departments to be 'necessary' by specifically preserving OPPS payment rates for those services when it addressed the matter in 2015."). Similarly, Plaintiffs suggest that Congress mandated that HHS pay a specific rate for clinic visits provided at excepted off-campus PBDs. *See* Pls.' Mem. at 26 (referring to "statutorily-prescribed rates").

Plaintiffs vastly overstate what Congress actually did in Section 603. While Congress said that excepted off-campus PBDs should remain in the OPPS as a general matter, it did not alter HHS's authority under paragraph (2)(F) to implement methodologies that may affect those rates for specific types of services. And Congress certainly did not carve in stone the rate that HHS pays for clinic visits provided at excepted off-campus PBDs; it merely established that excepted off-campus PBDs will continue to be paid through the OPPS. Nothing in Section 603 suggests—as Plaintiffs claim—that Congress determined that each and every service excepted off-campus PBDs provide are permanently "necessary" from now to the end of time, no matter how dramatically the volume of those services increases. Thus, this case is nothing like *Hays v. Sebelius*, 589 F.3d 1279

(D.C. Cir. 2009)—relied on by Plaintiffs—where Congress had "minutely detailed the reimbursement rates for covered items and services." Pls.' Mem. at 24 (quoting *Hays*, 589 F.3d at 1282).

Nor does HHS's development of a paragraph (2)(F) method to reduce the volume of OPD services erode the distinction Congress created in Section 603, as Plaintiffs suggest. Far from it. Excepted off-campus PBDs are still paid under the OPPS and receive the standard OPPS payment amount for all other items and services normally paid under the OPPS. Conversely, non-excepted PBDs are paid under the PFS for most items and services and receive the site-specific PFS payment rate for those items and services—rates that are usually lower than the OPPS payment rates the excepted PBDs receive. Excepted PBDs thus continue to receive the standard OPPS payment amount for emergency department visits, observation services, x-rays, cardiac catheterizations, and every one of the thousands of procedures usually paid under the OPPS, other than clinic visit services, where HHS established payment parity between the amount paid to excepted PBDs under the OPPS and non-excepted PBDs under the PFS.

In other words, the 2020 Rule targets only a single type of service for which HHS determined that there has been an unnecessary increase in volume and that can be provided safely in a non-hospital setting. Clearly then, and notwithstanding Plaintiffs' argument, the distinction Congress created in Section 603 continues to have import. Aside from clinic visit services, which HHS determined have increased unnecessarily in volume and for which the agency accordingly exercised its authority under paragraph (2)(F), services furnished by providers billing under the OPPS as of November 1, 2015 continue to be paid at higher OPPS rates, while services furnished by providers that were not billing under the OPPS as of November 1, 2015 are paid at lower PFS rates. Accepting Plaintiffs' argument would require HHS to prioritize, impermissibly, the

distinction Congress created in Section 603 over Congress's express requirement in paragraph (2)(F) of the same statute that HHS "shall" develop methods to control unnecessary increases in the volume of covered OPD services.

3. Plaintiffs also claim that HHS never made a finding that the increase in the volume of the relevant services were unnecessary. *See* Pls.' Mem. at 25-26. But Plaintiffs' argument is plainly incorrect. As HHS explained in the preamble to the 2019 Rule—the second phase of which the 2020 Rule implements—there have been unnecessary increases in volume of routine clinic visit services provided at off-campus PBDs. *See* 83 Fed. Reg. at 59,006-08. The volume of those services has continued to increase disproportionately, making clear that Congress's 2015 steps had not adequately addressed the financial incentives driving the increase. *See id.* at 59,008. At the same time, the volume of the same or similar services provided in physician offices has grown only minimally, underscoring that the growth in volume is due to the financial incentive of higher payment rates in the OPD setting. *Id.* at 59,006. This is precisely the type of situation contemplated by Congress when it directed that HHS "shall develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F). HHS therefore made the necessary predicate finding that there was an unnecessary increase in the volume of a particular type of outpatient service (routine clinic visits) and appropriately exercised its paragraph (2)(F) authority based on that finding.

B. The Statute Does Not Bar HHS From Exercising Its Paragraph (2)(F) Authority in a Non-Budget-Neutral Manner

Plaintiffs also contend that HHS acted unlawfully, because, according to Plaintiffs, the statute allows rates for specific services to be reduced only if HHS does so in a budget neutral manner. *See* Pls.' Mem. at 26-28. But again, Plaintiffs provide no logical reason why Congress

would have wanted HHS to create a windfall by increasing payment rates elsewhere in order to control an unnecessary increase in the volume of a single type of service.

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

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

Congress left the question of budget neutrality in paragraph (2)(F) to the agency's discretion when implementing that provision.

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

Plaintiffs' other argument is that the Rule is *ultra vires* because it allegedly conflicts with the distinction in the Medicare statute between excepted and non-excepted PBDs. *See* Pls.' Mem. at 28-31. Plaintiffs are incorrect.

Congress enacted Section 603 to address a particular problem: hospitals were buying up freestanding physician practices and converting the billing from the physician fee schedule to the higher outpatient department rate, "without a change in either the physical location or a change in the acuity of the patients seen." 83 Fed. Reg. at 59,008; *see also, e.g.*, Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy* 69-70 (Mar. 2017), https://go.usa.gov/xdCzG; U.S. Gov't Accountability Office, GAO-16-189, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform* (Dec. 2015), https://go.usa.gov/xdpQV.

To curb that practice, Section 603 removed from the OPPS those off-campus outpatient departments that would be established after Section 603 was enacted. *See* Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597-98, codified at 42 U.S.C. § 1395*l*(t)(1)(B)(v), (21). (The following year, Congress clarified that this exclusion from the OPPS did not apply to certain hospitals that were "mid-build" at the time Section 603 was enacted. *See* 21st Century Cures Act, Pub. L. No. 114-255, § 16001, 130 Stat. 1033, 1324 (2016).)

As a result of these amendments to the Medicare statute, newly established off-campus outpatient departments (sometimes referred to as "non-excepted PBDs") are paid at the physician fee schedule rate for *all* of the services they provide. In other words, these facilities were removed

from the OPPS altogether. By contrast, preexisting off-campus outpatient departments (sometimes referred to as "excepted PBDs") remain under the OPPS. As discussed above, these facilities continue to receive the standard OPPS payment amount for all other procedures usually paid under the OPPS. And crucially, because preexisting off-campus outpatient departments remain under the OPPS, they also remain subject to the specific OPPS volume-control authority in paragraph (2)(F). In the Rule at issue here, HHS properly exercised that paragraph (2)(F) authority with respect to a particular outpatient department service—routine clinic visits—based on the finding that there has been an unnecessary increase in the volume of those outpatient department services.

Contrary to Plaintiffs' contention, nothing in Section 603 exempts them from the Secretary's paragraph (2)(F) authority, or ensures that they would be reimbursed for every service at the OPPS rate, regardless of whether there was an unnecessary increase in volume of a particular service. There is no such guarantee in the statute, which simply leaves preexisting off-campus outpatient departments subject to the same OPPS provisions that govern outpatient departments generally. The amendments made by Section 603, which are codified in 42 U.S.C. § 1395*l*(t)(1)(B)(v), (21), did not in any way restrict the Secretary's authority under paragraph (2)(F) with respect to facilities that remain subject to the OPPS. Likewise, as discussed above, Section 603 did not purport to determine whether an increase in volume of a particular type of outpatient service was "necessary." *See* pp. 20, *supra*. Congress left that fact-specific determination to the Secretary to make through rulemaking under paragraph (2)(F), which Section 603 did not amend. Here, of course, the agency has properly exercised that authority, after making the predicate findings that there was an unnecessary increase in the volume of a particular type of outpatient service (routine clinic visits).

Plaintiffs rely on the statute's legislative history to attempt to bolster their claim that HHS must leave in place the OPPS rate for every service they provide. *See* Pls.' Mem. at 29 (citing H.R. Rep. No. 114-604, at 10 (2016)). It is unnecessary to look to legislative history because the statute itself authorizes HHS's actions, for the reasons explained above. *See Halverson v. Slater*, 129 F.3d 180, 187 n.10 (D.C. Cir. 1997). Yet, even so, contrary to Plaintiffs' suggestion, the 2016 House report did not guarantee preexisting off-campus facilities would receive the OPPS rate for all services. The House report simply stated, as a descriptive matter, that preexisting off-campus facilities "continue to receive the higher payment rates that apply to an outpatient department on the campus of a hospital," H.R. Rep. No. 114-604, pt. 1, at 20 (2016). That description was accurate at the time and remains so today for nearly every type of service these facilities provide. It is equally clear, however, that such "grandfathered" facilities, *id*. at 10, remain subject to the entirety of the OPPS, which includes the volume-control authority in paragraph (2)(F). Nothing in Section 603 gave preexisting off-campus outpatient departments special OPPS privileges or immunities that other outpatient departments do not enjoy.

Finally, Plaintiffs rely on HHS's prior statements to suggest that HHS "acknowledged Section 603's obvious purpose and conceded that [the Secretary] lacked the authority to revisit Congress's decision." Pls.' Mem. at 30 (citing GAO-16-189, *Increasing Hospital-Physician Consolidation Highlights Need for Payment Reform* 16 (Dec. 2015) (GAO Report), https://go.usa.gov/xdpQV)). Plaintiffs are incorrect. HHS has not previously determined the extent of its authority under paragraph (2)(F). Indeed, in the report Plaintiffs cite, the GAO recognized that HHS had provided only "technical comments" on a draft of the report. GAO Report at 17.

In any event, HHS has now issued the 2019 Rule and the 2020 Rule, utilizing its paragraph (2)(F) authority to control unnecessary increases in service volume, and the question before this

Court is whether HHS may do so under the Medicare Act. HHS respectfully submits that the answer is yes. As shown above, neither the text nor the purpose of the statute requires HHS to make across-the-board cuts to payment rates for *all* services, or to take only budget-neutral action, when it finds that there has been an unnecessary increase in volume for only a subset of services. Plaintiffs' contrary reading would seriously undermine the agency's ability to appropriately address unnecessary services while avoiding unfair payment cuts to necessary and appropriate services.

III. COLLATERAL ESTOPPEL DOES NOT PREVENT IMPLEMENTATION OF THE 2020 RULE—BUT IF THERE IS ANY DOUBT, THE COURT SHOULD STAY CONSIDERATION OF THE PARTIES' MOTIONS

Plaintiffs argue, finally, that HHS is estopped from applying the relevant portion of the 2020 Rule to most of them, in light of Judge Collyer's decision in *AHA I*. *See* Pls.' Mem. at 31-32. The obvious flaw in Plaintiffs' argument, of course, is that Defendants have appealed Judge Collyer's decision. That decision is therefore not yet final, and there is significant uncertainty whether it will be upheld on appeal. HHS should therefore not be estopped from implementing the second phase of the method Plaintiffs challenge in the 2020 Rule, which applies only to the 2020 calendar year.

Plaintiffs cite *Martin v. Malhoyt*, 830 F.2d 237 (D.C. Cir. 1987), for the proposition that *AHA I* has preclusive effect, even though an appeal is pending. But in that case, while the D.C. Circuit recognized that an appeal does not "automatically" deprive a decision of preclusive effect, *id.* at 264, it also explained that "[a]ccording preclusive effect to a judgment from which an appeal has been taken [ ] risks denying relief on the basis of a judgment that is subsequently over-turned," *id.* Thus, "care should be taken in dealing with judgments that are final, but still subject to direct review." *Id.*

The D.C. Circuit explained that "[o]ne potential solution . . . is to defer consideration of the preclusion question until the appellate proceedings addressed to the prior judgment are concluded, provided they are moving forward with reasonable dispatch and will not be long delayed." *Id.* at 265. Defendant would have no objection to the Court pursuing that course here. Defendant's appeal in *Kansas I* is proceeding "with reasonable dispatch." *Id*. The parties, including many of the Plaintiffs in this case, have completed briefing, and oral argument is currently scheduled for April 17, 2020. *See Am. Hosp. Ass'n v. Azar*, No. 19-5352, Order (D.C. Cir. Feb. 10, 2020). If the Court has concerns regarding collateral estoppel, the proper course would be to await a decision from the D.C. Circuit in the pending appeal regarding the first phase of HHS's challenged method to control an unnecessary increase in the volume of services.

IV. IF PLAINTIFFS PREVAIL, REMAND IS THE APPROPRIATE REMEDY

For the reasons above, Plaintiffs cannot succeed on the merits of their claims. However, if the Court were to conclude—contrary to Defendant's arguments—that HHS lacked authority under paragraph (2)(F) to control the unnecessary increase in the volume of clinic visit services through the Rule, the proper remedy would not be to enter an injunction ordering that HHS change its payment policies and provide immediate payments to Plaintiffs at the pre-Rule rate, as Plaintiffs demand. *See* Am. Compl., Relief Requested. Rather, the only appropriate remedy would be to remand to the agency for further consideration.

In reviewing agency action, the Court "ha[s] no jurisdiction to order specific relief," like an injunction. *Palisades Gen. Hosp., Inc. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). Instead, "'under settled principles of administrative law, when a court . . . determines that an agency made an error . . . , the court's inquiry is at an end: the case must be remanded to the agency for further action' . . . . consistent with [its opinion]." *Id.* (quoting *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999)); *see, e.g.*, *INS v. Ventura*, 537 U.S. 12, 16 (2002) (In reviewing an APA

claim, a court "'is not generally empowered to conduct a *de novo* inquiry . . . and to reach its own conclusions based on such an inquiry.' . . . Rather, 'the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."' (quoting *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985))). Accordingly, even if Plaintiffs' claims had merit—which they do not—a remand to HHS would be the only appropriate remedy.

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, if the Court has concerns that HHS may be collaterally estopped from applying the challenged portion of the 2020 Rule to Plaintiffs, Defendant respectfully asks that the Court stay a decision on the parties' motion pending resolution of Defendant's appeal to the D.C. Circuit in *AHA I* and *Kansas I*.

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