IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANT'S OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND MEMORANDUM IN SUPPORT OF MOTION TO DISMISS OR, IN THE ALTERNATIVE, CROSS-MOTION 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. 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.

The rule Plaintiffs challenge is an attempt to solve the problem, and to neutralize the financial incentive to increase OPD clinic visits, thereby eliminating wasteful spending and protecting beneficiaries from high out-of-pocket costs. For too long, Medicare was footing the bill for unnecessary clinic visits to OPDs because it was paying those departments more than it was paying physicians in freestanding practices for providing those same services. This state of affairs was bad for the Medicare system, which needs to stretch every federal dollar as far as possible in an era of exploding healthcare costs. And it was bad for Medicare beneficiaries, who have to cover a co-pay that is a percentage of the cost of the services provided to them.

Enter the challenged rule. *See* Medicare Program; Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, Proposed Rule, 83 Fed. Reg. 58,818 (Nov. 30, 2018) ("Rule"). The Centers for Medicare & Medicaid Services ("CMS") found that there was an unnecessary increase in the

volume of a subset of OPD services—specifically, those billed under the "clinic visit services" billing code, reserved for patient evaluation and management, and provided "off campus" (*i.e.*, not on the physical campus of a hospital or near a remote hospital facility)—and that those services can safely be provided in a non-hospital setting. Accordingly, to control the unnecessary increase in the volume of clinic visit services, CMS will pay for them under the same rate that it uses to pay off-campus provider-based departments that are paid under the Physician Fee Schedule.

Plaintiffs contend 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 CMS—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

[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's uses the term "off-campus PBD" as appropriate.

schedule—from exercising its broad statutory authority to otherwise control increases in the volume of those services. And, indeed, Plaintiffs' interpretation would effectively read out of the Medicare statute CMS'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' fallback argument is that the Rule is not a proper exercise of CMS's authority to control unnecessary increases in the volume of services, because, according to Plaintiffs, CMS, in fact, did not employ a "method." Plaintiffs are wrong. Plaintiffs narrowly read the Medicare statute to authorize CMS action only if it is an across-the-board reduction in Medicare payments. *See* Mem. of P. & A. in Supp. of Pls.' Mot. for Summ. J., Feb. 15, 2019, ECF No. 7-1, at 22-24 ("Pls.' SJ Mem."). But the statute does not require CMS to make across-the-board changes to the Medicare payment structure 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 CMS 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 argue, finally, that the Rule is invalid because it is not budget neutral. But the statutory provision that underpins the Rule, 42 U.S.C. § 1395*l*(t)(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 CMS is acting to address an *unnecessary* increase in

the volume of services. Otherwise, CMS's actions would only create a windfall to other providers, because, if Plaintiffs' theory were correct, CMS would need to overcompensate them to offset any reduction implemented to address unnecessary volume increases.

Accordingly, as more fully explained below, the Court should deny Plaintiffs' motion for summary judgment and dismiss this case, or enter summary judgment in favor of Defendant.

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

CMS, the agency within the U.S. Department of Health and Human Services responsible for administering Medicare, pays for OPD services under the Outpatient Prospective Payment System ("OPPS"). By contrast, most *inpatient* hospital services are paid under a separate payment system. Under the OPPS, CMS 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 Subsection (t)(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

[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."

59,006. MedPAC has documented how this growth is due in part to hospitals purchasing 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* Rule, 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*

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, 498 (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, CMS 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* Rule, 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

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Shift in Site of Care for Chemotherapy Administration (June 2014), https://www.thinkbrg.com/media/publication/454_Site_of__Care_Chemotherapy.pdf.

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 Rule

To address the persistent and unnecessary increases in the volume of clinic visit services provided at excepted off-campus PBDs, CMS sought notice and comment on a proposal to use its authority under Subsection (t)(2)(F) to pay for outpatient clinic visit services provided at those locations at the same rate that CMS 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, CMS adopted the proposal with minor alterations and published the Rule in the Federal Register on November 21, 2018. *See generally* Rule, 83 Fed. Reg. at 59,013.

In the Rule, CMS 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 CMS'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 prudent for the Medicare program to pay more for these services in one setting than another."). As explained in the Rule, CMS 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. CMS will phase in this method for controlling the unnecessary increases in the volume of clinic visit services over two years. *Id.* at 59,914. CMS estimates that, in 2019 alone, its method will result in savings of approximately $300 million to Medicare and approximately $80 million to Medicare beneficiaries in the form of reduced copayments. *Id.*

D. Plaintiffs' Complaint and Request for Summary Judgment

On March 13, 2019, Plaintiffs filed their second amended complaint in this action against the Secretary of Health and Human Services in his official capacity. Second Am. Compl., ECF No. 11-1. In their second amended complaint, Plaintiffs assert that they have each been paid for services at payment rates affected by the Rule and have each presented claims to Defendant seeking additional reimbursement at the pre-Rule rate. *Id.* ¶ 15. Plaintiffs also allege that further administrative review of Plaintiffs claims would be futile. *Id.*

Plaintiffs assert that the 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.* ¶¶ 52-57, 58-63. Plaintiffs seek declaratory and injunctive relief (i) preventing Defendant from implementing its method to control unnecessary increases in volume and (ii) requiring CMS to provide payments for clinic visit OPD services at the pre-Rule OPPS amount. *See id.*, Relief Requested. On February 15, 2019, Plaintiffs moved for summary judgment.

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' APA 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. 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 2019 OPPS 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 will likely 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* Second Am. Compl. ¶ 8. 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, Second Am. Compl. ¶ 15, 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. 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).

[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 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).

II. PLAINTIFFS' CLAIMS FAIL ON THE MERITS.

A. Standard of Review

Even if Plaintiffs could somehow surmount the obstacles described above and show that this Court should review CMS's development of the volume control method in the Rule, Plaintiffs' claims still would fail, because the Court must defer to CMS's interpretation of its authority under Subsection (t)(2)(F) based on *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837 (1984). The *Chevron* framework applies to judicial review of claims, like those here, that "an agency has acted 'in excess of statutory jurisdiction, authority or limitations.'" *Cmty. Health Sys., Inc. v. Burwell*, 113 F. Supp. 3d 197, 211-12 (D.D.C. 2015) (citing *Am. Fed'n of Gov't Emps. AFL-CIO, Local 3669 v. Shinseki*, 709 F.3d 29, 33 (D.C. Cir. 2013)). 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).

B. Congress Gave CMS the Authority to Control Unnecessary Increases in the Volume of OPD Services, Including Those Provided at Excepted Off-Campus PBDs.

Plaintiffs argue that the Rule is unlawful because, in Plaintiffs' view, it runs contrary to the distinction Congress created in Section 603 between excepted and non-excepted off-campus PBDs. *See* Pls.' SJ Mem. at 17-20. Plaintiffs, however, give far too much import to that distinction, overstate the effect of the Rule, and choose to ignore Congress's other, equally important directive in Subsection (t)(2)(F).

By amending the definition of "covered OPD services," Section 603 removed hospital outpatient departments from the OPPS altogether if they did not bill under that system as of November 1, 2015. *See* 42 U.S.C. § 1395*l*(t)(1)(B)(v); *see also id.* § 1395*l*(t)(21)(B)(ii). Departments that did bill under the OPPS system as of that date, so-called "excepted PBDs," continue to be paid under the OPPS, and therefore are subject to CMS's authority to administer that system, including the authority under Subsection (t)(2)(F) to develop methodologies to control unnecessary increases in the volume of covered OPD services.

In Plaintiffs' view, however, by creating a distinction between off-campus PBDs based on whether the PBD was billing in the OPPS system as of November 1, 2015, Congress meant to enshrine forever OPPS rates for excepted PBDs for all services that they provide, despite—and, indeed, at odds with—Congress's requirement that CMS deploy methods to control unnecessary increases in the volume of OPD services in Subsection (t)(2)(F). Plaintiffs' argument is essentially an extension of the *expressio unius* canon of construction—that, because Congress excluded certain providers from its payment reductions, CMS may never use its congressionally delegated Subsection (t)(2)(F) authority in a way that affects payments to those providers. As

the D.C. Circuit has explained, "[t]he *expressio unius* canon is a 'feeble helper in an administrative setting, where Congress is presumed to have left to reasonable agency discretion questions that it has not directly resolved.'" *Adirondack Med. Ctr.*, 740 F.3d at 697 (citation omitted). The canon provides "'too thin a reed to support the conclusion that Congress has clearly resolved an issue.' And when countervailed by a broad grant of [statutory] authority contained within the same statutory scheme, the canon is a poor indicator of Congress's intent." *Id*. (citations omitted).

So too here. In Section 603, Congress took steps to address, in part, the increasing costs of OPD services by expressly creating a relatively small subset of providers that would be excluded from the OPPS. *See* 42 U.S.C. § 1395*l*(t)(21)(C). But nothing in Section 603 prevents CMS, having determined that there has been an unnecessary increase in the volume of a specific OPD service among providers who remain in the OPPS system, from exercising its separate Subsection (t)(2)(F) authority to control the volume of that service. Again, notwithstanding the revisions Congress made through Section 603, Subsection (t)(2)(F) still requires CMS to "develop a method for controlling unnecessary increases in the volume of covered OPD services," and services provided by excepted PBDs remain "covered OPD services" following Congress's enactment of Section 603. *See id.* § 1395(t)(21)(B).

In an attempt to sidestep Subsection (t)(2)(F), Plaintiffs advance the novel argument that, in Section 603, Congress determined that all services provided in an excepted off-campus PBD are "necessary"—and therefore not subject to CMS's Subsection (t)(2)(F) authority. Pls.' S.J. Mem. at 19; *see also id.* at 21 ("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 CMS pay a specific rate for clinic visits provided at excepted off-campus PBDs. *See* Pls.' S.J. Mem. at 25-26; *see also id.* at 27 (referring to "statutorily-prescribed rates").

But 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 CMS's authority under Subsection (t)(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 CMS 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 increase. 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.' S.J. Mem. at 25 (quoting *Hays*, 589 F.3d at 1282).

Nor does CMS's development of a Subsection (t)(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 CMS established payment parity between the amount paid to excepted PBDs under the OPPS and non-excepted PBDs under the PFS.

In other words, the Rule targets only a single type of service for which CMS 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' exaggeration, the distinction Congress created in Section 603 continues to have import. Aside from clinic visit services, which CMS determined have increased unnecessarily in volume and for which the agency accordingly exercised its authority under Subsection (t)(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 CMS to prioritize, impermissibly, the distinction Congress created in Section 603 over Congress's express requirement in Subsection (t)(2)(F) of the same statute that CMS "shall" develop methods to control unnecessary increases in the volume of covered OPD services. As CMS explained in the preamble to the Rule, there have been unnecessary increases in volume of clinic visit services provided at off-campus PBDs. *See* Rule, 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 CMS "shall develop a method for controlling unnecessary increases in the volume of covered OPD services." 42 U.S.C. § 1395*l*(t)(2)(F).

C. CMS Properly Exercised Its Delegated Authority To Develop a Method To Control Unnecessary Increases in the Volume of Clinic Visit Services Provided at Excepted Off-Campus PBDs.

In the Rule, CMS 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 CMS acted unlawfully, because (1) the method that CMS employed is actually an adjustment, which must be budget neutral, and (2) the only permissible non-budget neutral adjustments are those that are applied as across-the-board cuts. *See* Pls.' SJ Mem. at 21-29. But Plaintiffs misread the Medicare Act and selectively cite statutory provisions in an attempt to limit the Secretary's authority under Subsection (t)(2)(F), where no such limitation exists.

Plaintiffs contend that Subsection (t)(2)(F) alone cannot authorize the rate reductions in the Rule because, according to Plaintiffs, Subsection (t)(9)(C) dictates the *only* way CMS may change payment rates pursuant to its Subsection (t)(2)(F) authority. Pls.' SJ Mem. at 23. But Plaintiffs' reading of Subsections (t)(2)(F) and (t)(9)(C) would lead to absurd results that Congress plainly did not intend. In Plaintiffs' view, if CMS were to conclude that there is an "unnecessary increase[] in the volume" of a single covered OPD service, 42 U.S.C. § 1395(t)(2)(F), its only non-budget neutral recourse would be to make an across-the-board adjustment to payment rates affecting *all services*. *See* Pls.' S.J. Mem. at 23. Plaintiffs provide no logical reason why Congress would have wanted CMS 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, CMS interprets Subsection (t)(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 CMS's interpretation of its authority. Subsection (t)(9)(C) states that the Secretary "*may* appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year" if "the Secretary determines under the methodologies described in [Subsection (t)(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 CMS "may" adjust the conversion factor—is entirely permissive and, contrary to Plaintiffs' claim, does not tie CMS'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 CMS's authority under Subsection (t)(9)(C) stands in stark contrast with the clear directive in Subsection (t)(2)(F) that CMS "shall" control unnecessary volume increases by

developing a methodology to control them, further suggesting that CMS has options other than a conversion factor adjustment to implement a methodology (*e.g.*, by reducing payment rates, as CMS did in the Rule).

Plaintiffs also point to what they call the "common-sense meaning" of Subsection (t)(2)(F) to argue that CMS may only implement that subsection through across-the-board cuts. Pls.' S.J. Mem. at 23. 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 CMS 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. 59,009. And, despite Plaintiffs' argument to the contrary, the dictionary definitions of "method" are entirely consistent with CMS'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.' S.J. Mem. at 23 (quoting Black's Law Dictionary at 1141 (10th ed. 2014). Here, CMS 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, CMS'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.' S.J. Mem. at 23 (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 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, CMS's action in the Rule falls comfortably within the meaning of "method."

Plaintiffs also argue, incorrectly, that any changes to payment rates for individual services must be budget neutral if they do not apply across-the-board through Subsection (t)(9)(C). *See* Pls.' S.J. Mem. at 24, 27-29. The budget neutrality provision at the heart of Plaintiffs' argument, Subsection (t)(9)(B), however, applies on its face only to the periodic rate adjustments made under Subsection (t)(9)(A). Specifically, Subsection (t)(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). By its clear terms, that budget neutrality requirement in Subsection (t)(9)(B) does *not* apply when CMS exercises its separate authority under Subsection (t)(2)(F).

The absence of a budget-neutrality requirement in Subsection (t)(2)(F) is consistent with the purpose of that provision. As Plaintiffs acknowledge, the purpose of Subsection (t)(9)(A) is to allow for budget-neutral rate adjustments for specific reasons articulated in the statute, such as changes in medical technology. *See* 42 U.S.C. § 1395*l*(t)(9)(A). In order to implement a method under Subsection (t)(2)(F), however, the Secretary must first identify an *unnecessary* increase in the volume of a covered service. Thus, Subsections (t)(9)(A) and (t)(2)(F) serve different functions. To the degree there are *unnecessary* increases in the volume of some services, it is perfectly natural, and consistent with the goals of the Balanced Budget Act of 1997, that Congress would want these unnecessary increases in volume controlled in a non-budget-neutral manner that applies only to those specific services. Otherwise, CMS would be forced to make unfair, across-the-board cuts, or allow unnecessary services to continue to drive up costs to Medicare irreversibly.

Plaintiffs' argument that the method developed in the Rule is subject to Subsection (t)(9)(A) because it resembles an "adjustment" must fail for similar reasons. *See* Pls.' S.J. Mem. at 27-29. While, in this instance, the method CMS developed results in lower payment rates for some services, it is not, in fact, an "adjustment" as that term is used in the statute, because it is premised on CMS's finding of an unnecessary increase in the volume of services. Accordingly, Plaintiffs are incorrect that Subsection (t)(9)(A) applies on its face to Subsection (t)(2)(F). *See* Pls.' S.J. Mem. at 28-29. Subsection (t)(9)(A) refers to "rev[isions to] the groups, the relative payment weights, and the wage and other adjustments described in [Subsection (t)(2)]." 42 U.S.C. § 1395*l*(t)(9)(A). Conspicuously absent from Subsection (t)(9)(A) is a reference to any "method" developed under Subsection (t)(2)(F), as opposed to the "adjustments" elsewhere in Subsection (t)(2), which further supports CMS's interpretation that the budget neutrality requirement in Subsection (t)(9)(B) does not limit CMS's action in the Rule.

Nor does Subsection (t)(2)(F), unlike other similar provisions, itself contain a free-standing budget neutrality requirement. By contrast, in the two subsections directly preceding Subsection (t)(2)(F), Congress included a budget neutrality requirement when giving CMS the authority to make certain other payment changes. In Subsection (t)(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 Subsection (t)(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 Subsection (t)(2)(F).

Because Congress has shown in the Medicare Act that it knows how to require budget neutrality when it wants to, this Court should be reluctant to read into Subsection (t)(2)(F) any requirement for budget neutrality in the absence of express statutory language. *See, e.g.*, *Franklin Nat'l Bank v. New York*, 347 U.S. 373, 378 (1954) (finding "no indication that Congress intended to make this phase of national banking subject to local restrictions, as it has done by express language in several other instances"); *Meghrig v. KFC Western, Inc.*, 516 U.S. 479, 485 (1996) ("Congress . . . demonstrated in CERCLA that it knew how to provide for the recovery of cleanup costs, and . . . the language used to define the remedies under RCRA does not provide that remedy"); *FCC v. NextWave Pers. Commc'ns, Inc.*, 537 U.S. 293, 302 (2003) (when Congress has intended to create exceptions to bankruptcy law requirements, "it has done so clearly and expressly"); *Dole Food Co. v. Patrickson*, 538 U.S. 468, 476 (2003) (Congress knows how to refer to an "owner" "in other than the formal sense," and did not do so in the Foreign Sovereign Immunities Act's definition of foreign state "instrumentality"); *Whitfield v. United States*, 543 U.S. 209, 215-17 (2005) (observing that Congress has imposed an explicit overt act requirement in twenty-two conspiracy statutes, yet has not done so in the provision governing conspiracy to commit money laundering). Indeed, Congress's silence in Subsection (t)(2)(F) as to whether CMS's methods to control unnecessary volume increases must be budget neutral suggests that Congress left the question to agency discretion.

As shown above, neither the text nor the purpose of the statute requires CMS 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 service increases while avoiding unfair payment cuts to necessary and appropriate services.

III. PLAINTIFFS SEEK AN INAPPROPRIATE FORM OF RELIEF.

For all 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 CMS lacked authority under Subsection (t)(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 CMS change its payment policies and provide immediate payments to Plaintiffs at the pre-Rule rate, as Plaintiffs demand. *See* Second 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.* (some internal quotation marks omitted) (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 CMS would be the only appropriate remedy.

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court deny Plaintiffs' motion for summary judgment and dismiss the case. In the alternative, Defendant asks that the Court enter summary judgment in Defendant's favor.

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Respectfully submitted,

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