**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF COLUMBIA**

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| **AMERICAN HOSPITAL ASSOCIATION, *et al.*,** | ) | |
| **Plaintiffs,** | ) | |
| **v.** | ) | **Civil Action No. 18-2841 (RMC)** |
| **ALEX M. AZAR II, Secretary of the Department of Health and Human Services,** | ) | |
| **Defendant.** | ) | |

**MEMORANDUM OPINION**

Under Medicare Part B, the Centers for Medicare & Medicaid Services (CMS) pays hospital outpatient departments at predetermined rates for patient services, and Congress has established the Outpatient Prospective Payment System by which CMS is to set and pay those rates. CMS came to believe that the rate for certain clinic-visit services at a specific subset of these outpatient departments—familiarly, off-campus provider-based departments—was too high and that patients could receive similar services from free-standing physician offices at lower cost to the government and to taxpayers. Accordingly, CMS promulgated a rule in 2018 lowering the payment rate for clinic-visit services at off-campus provider-based departments to match the rate for similar services at physician offices, in order to shift patients towards the latter.

Plaintiffs are hospital organizations which have seen their payment rates cut. They argue that the method by which CMS has cut their rates has no place in the statutory scheme established by Congress, and further that Congress has already decided as a matter of policy and practicality that off-campus provider-based departments should be paid at *higher* rates

than physician offices for similar services. In short, Plaintiffs argue that CMS' 2018 rule is *ultra vires*. CMS opposes. Both parties move for summary judgment.

The Court has given close attention to the parties' arguments and the statutory scheme, which, as relevant, is both simple and detailed. For the reasons below, the Court finds that CMS exceeded its statutory authority when it cut the payment rate for clinic services at off-campus provider-based clinics. The Court will grant Plaintiffs' motion, deny CMS' cross-motion, vacate the rule, and remand.

## I. BACKGROUND

The Medicare program, established by Title XVIII of the Social Security Act, 42 U.S.C. § 1395 *et seq.*, provides federally funded medical insurance to the elderly and disabled. Medicare Part A addresses insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Medicare Part B addresses supplemental coverage for other types of care, including outpatient hospital care. *Id.* §§ 1395j, 1395k.

### A. The Outpatient Prospective Payment System

Under Medicare Part B, CMS directly reimburses hospital outpatient departments for providing outpatient department (OPD) services to Medicare beneficiaries, which payments are made through the elaborate Outpatient Prospective Payment System (occasionally, OPPS). *See generally* 42 U.S.C. § 1395*l*(t). Implemented as part of the Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251, the Outpatient Prospective Payment System does not reimburse hospitals for their actual costs of providing OPD services. Rather, as with Medicare generally and in an effort to control costs, the Outpatient Prospective Payment System pays for OPD services at pre-determined rates. *See Amgen, Inc. v. Smith*, 357 F.3d 103, 106 (D.C. Cir. 2004). Those payment rates are determined as follows: OPD services which are clinically comparable or which require similar resource usage are grouped together and assigned an

Ambulatory Payment Classification (occasionally, APC). 42 U.S.C. § 1395*l*(t)(2)(B). A formula is used to calculate the relative payment weight of each Ambulatory Payment Classification against other APCs, based on the average cost of providing OPD services in previous years. *See id.* § 1395*l*(t)(2)(C). Each Ambulatory Payment Classification's relative payment weight is then multiplied by an Outpatient Prospective Payment System "conversion factor"—which is the same for, and applies uniformly to, all APCs—to reach the fee schedule amount for each APC. *Id.* § 1395*l*(t)(3)(D). Ultimately, the actual amount paid to the hospital is the calculated fee schedule amount adjusted for regional wages, transitional pass-through payments, outlier costs, "and other adjustments as determined to be necessary to ensure equitable payments, such as adjustments for certain classes of hospitals," *id.* § 1395*l*(t)(2)(D)-(E), less an applicable deductible and modified by a "payment proportion." *See id.* § 1395*l*(t)(4).

Every year, CMS must review the groups, relative payment weights, and wage and other adjustments for each Ambulatory Payment Classification to account for changes in medical practice or technology, new services, new cost data, and other relevant information and factors. *Id.* § 1395*l*(t)(9)(A). This annual review is conducted with an important caveat: any adjustment to the groups, relative payment weights, or adjustments must be budget neutral, meaning that it cannot cause a change in CMS' estimated expenditures for OPD services for the year. *See id.* § 1395*l*(t)(9)(B); *cf. id.* § 1395*l*(t)(9)(D)-(E) (requiring initial wage, outlier, and other adjustments also be budget neutral). Thus, decreases or increases in spending caused by one adjustment must be offset with increases or decreases in spending by another.

CMS must also update annually the Outpatient Prospective Payment System conversion factor, generally to account for the inflation rate for the cost of medical services, *see id.* § 1395*l*(t)(3)(C)(iv), but sometimes for other reasons, as discussed below. Unlike

adjustments to Ambulatory Payment Classifications under paragraph (t)(9)(A), adjustments to the conversion factor do *not* need to be budget neutral. *See generally id.* § 1395*l*(t)(3)(C) (describing conversion factor inputs). However, because the same conversion factor applies equally to all Ambulatory Payment Classifications, adjustments to the conversion factor cannot be used to change the fee schedule for specific APCs. In other words, changes to the conversion factor affect total spending and not spending on specific services.

The Outpatient Prospective Payment System controls overall costs by incentivizing hospital outpatient departments to provide OPD services at or below the average cost for such services. That said, while the Outpatient Prospective Payment System limits the amount Medicare will pay for each service, it does not limit the volume or mix of services provided to a patient. Concerned that fee schedule limits would not adequately limit increases in overall expenditures, Congress included as part of the Outpatient Prospective Payment System two provisions at issue here. Under paragraph (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). Further, under paragraph (t)(9)(C), "[i]f 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, the Secretary may appropriately adjust the update to the conversion factor otherwise applicable in a subsequent year." *Id.* § 1395*l*(t)(9)(C).

### B. Off-Campus Provider-Based Departments, Physician Offices, and the Bipartisan Budget Act of 2015

Many medical services that were once only offered in an inpatient hospital setting can now be provided by hospital outpatient departments whereby the patient does not spend the night. Medicare traditionally welcomed these cheaper alternatives to inpatient care and, to meet

the growing demand for these services, some hospitals have established off-campus provider-based departments (occasionally, PBDs), which are outpatient departments at facilities separated by a specific distance (or more) from the physical campus of the hospital with which they are affiliated. *See* 42 C.F.R. § 413.65(e). Although not physically proximate to their affiliated hospital's main campus,[1] off-campus provider-based departments are so closely integrated into the same system that they are considered part of the hospital itself. This allows off-campus provider-based departments to offer more comprehensive services to their patients but also subjects off-campus provider-based departments to the same regulatory requirements as the main hospital. *See* 42 C.F.R. § 413.65 (describing regulatory requirements for off-campus provider-based departments). Because they are part of the same system and face the same regulatory requirements and regulatory costs as hospitals, off-campus provider-based departments have generally been paid at the same rates hospitals are paid for OPD services.[2]

That said, some comparable outpatient medical services can also be provided by free-standing physician offices, which are medical practices not integrated with, or part of, a hospital. *See* 42 C.F.R. § 413.65(a)(2). While physician offices do not provide the same array of services as off-campus provider-based departments, they also do not bear the same regulatory requirements and costs as hospitals. Accordingly, CMS pays physician offices for outpatient medical services according to the lower-paying Medicare Physician Fee Schedule instead of the Outpatient Prospective Payment System. As relevant to this case, in 2017 the Outpatient Prospective Payment System rate for the most voluminous OPD service provided by off-campus

[1] For example, an off-campus provider-based department may be located away from the main hospital because of space constraints at the main campus, or because the hospital wants to have an affiliated facility in a different (oftentimes underserved) neighborhood.

[2] Not all are paid the same amounts, for reasons described below.

provider-based departments, "evaluation and management of a patient" (E&M),[3] was $184.44 for new patients and $109.46 for established patients while the Physician Fee Schedule rate for the comparable service at a physician office was $109.46 for a new patient and $73.93 for an established patient. *See* 83 Fed. Reg. 37,046, 37,142 (July 31, 2018) (Proposed Rule).

Until 2015, all off-campus provider-based departments were paid according to the Outpatient Prospective Payment System. At that time, the volume of OPD services had increased by 47 percent over the decade ending in calendar year 2015 and, in the five years from 2011 to 2016, combined program spending and beneficiary cost-sharing (*i.e.*, co-payments) rose by 51 percent, from $39.8 billion to $60.0 billion. *See* Proposed Rule at 37,140. There are many possible explanations for this increase. For one, the Medicare-eligible population grew substantially during the same time period. *See* Medicare Board of Trustees, 2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 181 (2018), *available at* https://go.cms.gov/2m5ZCok. For another, advances in medical technology shifted services from inpatient settings to outpatient settings. *See* Ken Abrams, Andreea Balan-Cohen & Priyanshi Durbha, Growth in Outpatient Care, Deloitte (Aug. 15, 2018), *available at* https://bit.ly/2nOkG05.

However, the Medicare Payment Advisory Commission (MedPAC), an independent congressional agency which advises Congress on issues related to Medicare, long believed that another major reason for this increase was the financial incentive created by the Outpatient Prospective Payment System compared to the Physician Fee Schedule. *See* MedPAC, Report to the Congress: Medicare Payment Policy 69-70 (Mar. 2017). That is, because off-

[3] Technically, E&M services fall under Healthcare Common Procedure Coding System (HCPCS) code G0463, billed under APC 5012 (Clinic Visits and Related Services).

campus provider-based departments are paid at higher rates than physician offices, MedPAC advised that hospitals were buying existing physician offices and converting them into off-campus provider-based departments, sometimes without a change of location or patients, unnecessarily causing CMS to incur higher costs. *See id.* To combat this trend, MedPAC repeatedly recommended that Congress authorize CMS to equalize payment rates under both the Outpatient Prospective Payment System and Physician Fee Schedule for certain services, including E&M services, at all off-campus provider-based departments. *See id.* at 70-71; *see also id.* at 69 ("One-third of the growth in outpatient volume from 2014 to 2015 was due to an increase in the number of evaluation and management (E&M) visits billed as outpatient services."). Hospitals responded by advising Congress that MedPAC's recommendation ignored the higher costs required to operate a hospital and would force some existing off-campus provider-based departments, which relied on the rates set by the Outpatient Prospective Payment System, to reduce their services or close completely. *See, e.g.*, Letter from Atul Grover, Chief Pub. Policy Officer, Ass'n of Am. Med. Colls., to The Hon. John Barrasso, *et al*. (Jan. 13, 2012), *available at* http://bit.ly/2LVEXOT.

Congress ended the debate, at least momentarily, when it adopted Section 603 of the Bipartisan Budget Act of 2015, Pub. L. No. 114-74, § 603, 129 Stat. 584, 597 (2015). That 2015 statute neither equalized payment rates for physicians offices and off-campus provider-based departments, as MedPAC had recommended, nor left the Outpatient Prospective Payment System untouched, as the hospitals requested. Instead, Congress chose a middle path: Off-campus provider-based departments that were billing under the Outpatient Prospective Payment System as of November 2, 2015 (now "excepted off-campus PBDs") were permitted to continue that practice. *See* 42 U.S.C. § 1395*l*(t)(21)(B)(ii). However, off-campus provider-based

departments which were not billing under the Outpatient Prospective Payment System as of November 2, 2015, *i.e.*, *new* off-campus provider-based departments (or "nonexcepted off-campus PBDs"), would be paid according to a different rate system to be selected by CMS. *See id.* § 1395*l*(t)(21)(C). In practice, CMS continues to pay nonexcepted off-campus PBDs under the Outpatient Prospective Payment System but applies a "[Physician Fee Schedule] Relativity Adjustor" which approximates the rate the operative Physician Fee Schedule would have paid. *See* 81 Fed. Reg. 79,562, 79,726 (Nov. 14, 2016).

**C. The Final Rule and Plaintiffs' Challenge**

Despite these changes, the volume of OPD services provided by excepted off-campus provider-based departments grew. When Congress passed the Bipartisan Budget Act of 2015, expenditures by the Outpatient Prospective Payment System were approximately $56 billion and increasing at an annual rate of about 7.3 percent, with the volume and intensity of outpatient services increasing by 3.5 percent. *See* Proposed Rule at 37,139. In 2018, CMS estimated that, without intervention, expenditures in 2019 would rise to $75 billion (an increase of 8.1 percent over 2018), with the volume and intensity increasing by 5.3 percent. *See id.* at 37,139.

CMS thus proposed to implement a "method for controlling unnecessary increases in the volume of covered OPD services." *See generally id.* at 37,138-143; *cf.* 42 U.S.C. § 1395*l*(t)(2)(F). Specifically, CMS determined that many of the E&M services provided by off-campus provider-based departments were "unnecessary increases in the volume of outpatient department services." Such services were not deemed *medically* "unnecessary" but *financially* "unnecessary" because "these services could likely be safely provided in a lower cost setting,"

*i.e.*, at physician offices.[4] Proposed Rule at 37,142. More specifically, CMS determined that the growth of E&M services provided by off-campus provider-based departments was due to the higher payment rate available to excepted off-campus provider-based departments under the Outpatient Prospective Payment System. *Id.* CMS proposed to solve its financial problem by applying the corresponding Physician Fee Schedule rate for E&M services to excepted off-campus PBDs, thereby equalizing the payment rate for E&M services provided by excepted off-campus PBDs, nonexcepted off-campus PBDs, and physician offices alike. *Id.* at 37,142.

CMS also determined that it could not control the volume of financially "unnecessary" OPD services in a budget-neutral fashion, since this would "simply shift the movement of the volume within the OPPS system in the aggregate." *Id.* at 37,143. Therefore, CMS proposed to implement its new approach in a *non*-budget-neutral manner, asserting that the budget neutrality requirements of paragraphs (t)(2)(D)-(E) and (t)(9)(B) do not apply to "methods" developed under paragraph (t)(2)(F) and that its new approach constituted such a method. *Id.* CMS estimated that this approach would save approximately $610 million in 2019 alone. *Id.*

CMS received almost 3,000 comments on the Proposed Rule, many of which argued that CMS lacked statutory authority to implement the proposed method. Nonetheless, on November 21, 2018, CMS issued a Final Rule implementing the proposed method effective

[4] As a general matter, CMS uses expenditures over targeted levels to measure "unnecessary" increases in the volume of OPD services, albeit not without criticism. *See, e.g.*, 63 Fed. Reg. 47,552, 47,586 (Sept. 8, 1998) ("[W]e are examining a number of mechanisms to control unnecessary increases, as reflected by expenditure levels, in the volume of covered outpatient department services."); 65 Fed. Reg. 18,434, 18,503 (Apr. 7, 2000) ("Others argued that an expenditure target is not a reliable way to distinguish the growth of necessary versus unnecessary services."); 66 Fed. Reg. 44,672, 44,707 (Aug. 24, 2001) (noting MedPAC's recommendation that CMS "not use an expenditure target to update the conversion factor").

January 1, 2019. *See generally Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs*, 83 Fed. Reg. 58,818, 59,004-15 (Nov. 21, 2018) (Final Rule). The only substantive change between the Proposed Rule and the Final Rule was that implementation of the full E&M rate cut was staggered over two years, saving an estimated $300 million in 2019, with additional savings subsequent. *Id.* at 59,004.

Plaintiffs are hospital organizations and related trade groups that have provided services with payment rates affected by the Final Rule, have submitted claims for payment by Medicare, and have appealed determinations on those claims to CMS. The Defendant is Alex M. Azar, in his official capacity as the Secretary of the Department of Health and Human Services. Plaintiffs argue that the Final Rule is contrary to both the Medicare statutory scheme and the policy decision reached by Congress under Section 603 of the Bipartisan Budget Act of 2015 and is therefore *ultra vires*. Both parties have moved for summary judgment; the matter is now ripe.[5]

## II. LEGAL STANDARD

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *accord Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247 (1986). "In a case involving review of a final agency action under the Administrative Procedure Act, however, the standard set forth in Rule 56[] does

[5] On August 26, 2019, the Court consolidated two cases challenging the same Final Rule: *Am. Hosp. Ass'n v. Azar*, No. 18-2841 (RMC), and *Univ. of Kansas Hosp. Auth. v. Azar*, No. 19-132 (RMC). *See* 8/26/2019 Minute Order. Although each set of plaintiffs asserts a different legal vehicle to bring their claim—non-statutory review and APA review, respectively—both challenge the same Final Rule on purely legal grounds with largely overlapping, and not inconsistent, legal arguments. Both legal theories are addressed herein.

not apply because of the limited role of a court in reviewing the administrative record." *Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 89 (D.D.C. 2006) (internal citation omitted); *see also Charter Operators of Alaska v. Blank*, 844 F. Supp. 2d 122, 126-27 (D.D.C. 2012). Under the APA, the agency's role is to resolve factual issues to reach a decision supported by the administrative record, while "'the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did.'" *Sierra Club*, 459 F. Supp. 2d at 90 (quoting *Occidental Eng'g Co. v. INS*, 753 F.2d 766, 769-70 (9th Cir. 1985)). "Summary judgment thus serves as the mechanism for deciding, as a matter of law, whether the agency action is supported by the administrative record and otherwise consistent with the APA standard of review." *Id*. (citing *Richards v. INS*, 554 F.2d 1173, 1177 & n.28 (D.C. Cir. 1977)).

Plaintiffs' argument that the Secretary acted *ultra vires* is premised on three basic tenets of administrative law. First, "an agency's power is no greater than that delegated to it by Congress." *Lyng v. Payne*, 476 U.S. 926, 937 (1986); *see also Transohio Sav. Bank v. Dir.*, *Office of Thrift Supervision*, 967 F.2d 598, 621 (D.C. Cir. 1992). Second, agency actions beyond delegated authority are *ultra vires* and should be invalidated. *Transohio*, 967 F.2d at 621. Third, courts look to an agency's enabling statute and subsequent legislation to determine whether the agency has acted within the bounds of its authority. *Univ. of D.C. Faculty Ass'n/NEA v. D.C. Fin. Responsibility & Mgmt. Assistance Auth.*, 163 F.3d 616, 620-21 (D.C. Cir. 1998) (explaining that *ultra vires* claims require courts to review the relevant statutory materials to determine whether "Congress intended the [agency] to have the power that it exercised when it [acted]").

When reviewing an agency's interpretation of its enabling statute and the laws it administers, courts are guided by "the principles of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)." *Mount Royal Joint Venture v. Kempthorne*, 477 F.3d 745, 754 (D.C. Cir. 2007) (internal citations omitted). *Chevron* sets forth a two-step inquiry. The initial question is whether "Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 843. If so, then "that is the end of the matter" because both courts and agencies "must give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. To decide whether Congress has addressed the precise question at issue, a reviewing court applies "'the traditional tools of statutory construction.'" *Fin. Planning Ass'n v. SEC*, 482 F.3d 481, 487 (D.C. Cir. 2007) (quoting *Chevron*, 467 U.S. at 843 n.9). It analyzes "the text, structure, and the overall statutory scheme, as well as the problem Congress sought to solve." *Id.* (citing *PDK Labs. Inc. v. DEA*, 362 F.3d 786, 796 (D.C. Cir. 2004); *Sierra Club v. EPA*, 294 F.3d 155, 161 (D.C. Cir. 2002)). When the statute is clear, the text controls and no deference is extended to an agency's interpretation in conflict with the text. *Chase Bank USA, N.A. v. McCoy*, 562 U.S. 195 (2011).

If the statute is ambiguous or silent on an issue, a court proceeds to the second step of the *Chevron* analysis and determines whether the agency's interpretation is based on a permissible construction of the statute. *Chevron*, 467 U.S. at 843; *Sherley v. Sebelius*, 644 F.3d 388, 393-94 (D.C. Cir. 2011). Under *Chevron* Step Two, a court determines the level of deference due to the agency's interpretation of the law it administers. *See Mount Royal Joint Venture*, 477 F.3d at 754. Where, as here, "an agency enunciates its interpretation through notice-and-comment rule-making or formal adjudication, [courts] give the agency's interpretation *Chevron* deference." *Id.* at 754 (citing *United States v. Mead Corp.*, 533 U.S. 218,

230-31 (2001)). That is, an agency's interpretation that is permissible and reasonable receives controlling weight,[6] *id.*, "even if the agency's reading differs from what the court believes is the best statutory interpretation," *see Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005). Such broad deference is particularly warranted when the regulations at issue "concern[] a complex and highly technical regulatory program." *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (internal quotation marks and citation omitted).

## III. ANALYSIS

### A. Reviewability

The government contends that this Court lacks jurisdiction to review the Final Rule under the APA because Congress has precluded judicial review of the development of the Outpatient Prospective Payment System, including its methods and adjustments, and because Plaintiffs have failed to exhaust their administrative remedies under the Medicare statute.

*1. Preclusion of Judicial Review*

Agency action is subject to judicial review under the APA unless the statute precludes review, or the agency action is committed to agency discretion by law. *See COMSAT Crop. v. FCC*, 114 F.3d 223, 226 (D.C. Cir. 1997) (citing 5 U.S.C. § 701(a)). The statute specifies one such limitation:

> 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 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)*.

[6] An interpretation is permissible and reasonable if it is not arbitrary, capricious, or manifestly contrary to the statute. *Mount Royal Joint Venture*, 477 F.3d at 754.

42 U.S.C. § 1395*l*(t)(12)(A) (emphasis added). The government argues here that the Final Rule imposed a rate cut as a "method" developed under paragraph (t)(2)(F) and so court review is barred. *Cf. id.* § 1395*l*(t)(2)(F) ("[T]he Secretary shall develop a method for controlling unnecessary increases in the volume of covered OPD services.").

Despite the bar against Medicare review in some contexts, "[t]here is a strong presumption that Congress intends judicial review of administrative action, and it can only be overcome by a clear and convincing evidence that Congress intended to preclude the suit." *Amgen*, 357 F.3d at 111 (internal citations and quotations omitted). "The presumption is particularly strong that Congress intends judicial review of agency action taken in excess of delegated authority." *Id.* "Such review is favored . . . 'if the wording of a preclusion clause is less than absolute.'" *Id.* (quoting *Dart v. United States*, 848 F.2d 217, 221 (D.C. Cir. 1988)). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from 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, 346 (1984).

Applied to this case, paragraph (t)(12)(A) plainly shields a "method" to control volume in outpatient departments from judicial review. To determine whether that shield applies, though, the Court must ascertain, consistent with Plaintiffs' *ultra vires* claims, whether what CMS calls a "method" satisfies the statute. That is, CMS cannot shield any action from judicial review merely by calling it a "method," even if it is not that. Accordingly, "the determination of whether the court has jurisdiction is intertwined with the question of whether the agency has authority for the challenged action, and the court must address the merits to the extent necessary to determine whether the challenged agency action falls within the scope of the

preclusion on judicial review." *Id.* at 113; *see also COMSAT*, 114 F.3d at 227 ("The no-review provision . . . merges consideration of the legality of the [agency's] action with consideration of this court's jurisdiction in cases in which the challenge to the [agency's] action raises the question of the [agency's] authority to enact a particular amendment."). Because, as explained below, the Court finds that CMS' action here does not constitute a "method" within the meaning of the statute, the Court also finds that paragraph (t)(12)(A) does not preclude judicial review of Plaintiffs' claims.[7]

*2. Exhaustion*

As argued by the government, Section 405(g) of the Medicare statute requires a plaintiff to obtain administrative review of its claims before filing suit in court. *See* 42 U.S.C. § 405(g); *see also Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018) (describing the Medicare statute channeling provisions). Specifically, Section 405(g) has two requirements: (1) "presentment" of the claim; and (2) exhaustion of administrative remedies. *See Am. Hosp. Ass'n*, 895 F.3d at 825-26. The government does not substantially argue that Plaintiffs have failed to present their claim. But the government does argue that Plaintiffs have not fully availed themselves of the administrative review process. Plaintiffs concede that they have not exhausted their administrative remedies fully but argue that the requirement of exhaustion should be waived because further administrative review would be futile.

[7] Certain plaintiffs argue that they may bring a non-statutory *ultra vires* claim, even if review under the APA is precluded. *See* Reply in Supp. of Pls.' Mot. for Summ. J. [Dkt. 25] at 11-14. True, "the case law in this circuit is clear that judicial review is available when an agency acts *ultra vires*." *Aid Ass'n for Luterans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir 2003). But non-statutory claims may also be precluded and the standard for determining whether non-statutory review is limited is the same as under the APA. *See Dart*, 848 F.2d at 221 ("If the wording of a preclusion clause is less than absolute, the presumption of judicial review . . . is favored when an agency is charged with acting beyond its authority."). Thus, the analysis and outcome are the same.

"Futility may serve as a ground for excusing exhaustion, either on its own or in conjunction with other factors." *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 110 (D.D.C. 2015) (citing *Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992)). Futility applies where exhaustion would be "clearly useless," such as where the agency "has indicated that it does not have jurisdiction over the dispute, or because it has evidenced a strong stand on the issue in question and an unwillingness to reconsider the issue." *Randolph-Sheppard Vendors v. Weinberger*, 795 F.2d 90, 106 (D.C. Cir. 1986). That said, the ordinary standard for futility in administrative law cases is inapplicable in Medicare cases. *See Weinberger v. Salfi*, 422 U.S. 749, 766 (1975) (stating that § 405(g) 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"). In the context of Medicare, courts also look to whether "judicial resolution of the issue will interfere with the agency's efficient functioning, deny the agency the ability to self-correct, or deprive the Court of the benefits of the agency's expertise and an adequate factual record." *Nat'l Ass'n for Home Care & Hospice*, 77 F. Supp. 3d at 111 (citing *Tataranowicz*, 959 F.2d at 275); *see also Am. Hosp. Ass'n v. Azar*, 348 F. Supp. 3d 72, 75 (D.D.C. 2018), *appeal docketed*, No. 19-5048 (D.C. Cir. Feb. 28 2019).

Consideration of these factors makes clear that requiring Plaintiffs to exhaust their administrative remedies here would be a "wholly formalistic" exercise in futility. *Tataranowicz*, 959 F.2d at 274. The government does not argue that further administrative review is necessary for the agency's efficient functioning. Nor does the government argue that administrative review will give the agency the opportunity to self-correct. To the contrary, CMS' interpretation here is "even more embedded" since it was promulgated through notice-and-comment rulemaking whereby CMS has already considered and rejected Plaintiffs' specific arguments. *Nat'l Ass'n for*

*Home Care & Hospice*, 77 F. Supp. 3d at 112; Final Rule at 59,011-13. Finally, additional administrative review would do nothing to develop the factual record or provide the Court with further benefits of agency expertise, since this case concerns a purely legal challenge to the scope of the Secretary's statutory authority. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23-24 (D.D.C. 2009) ("[E]xhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law." (internal quotations omitted)). Indeed, it does not appear that further expertise can be brought to bear since no administrative review body has the authority to override CMS' binding regulations. *See* 42 C.F.R. § 405.1063(a) ("All laws and regulations pertaining to the Medicare and Medicaid programs . . . are binding on ALJs and attorney adjudicators, and the [Medicare Appeals] Council."); *see, e.g.*, Noridian Healthcare Solutions, *G0463 Has No Appeal Rights* (Mar. 22, 2019), *available at* http://bit.ly/2K2Yw4W ("CMS has provided direction to the Medicare Administrative Contractors (MACs) to dismiss requests appealing the reimbursement of HCPCS G0463. No further appeal rights will be granted at subsequent levels due to the statutory guidance supporting the pricing of this HCPCS code."). In short, the government "gives no reason to believe that the agency machinery might accede to plaintiffs' claims," even as it recites the formal steps involved in administrative review. *Tataranowicz*, 959 F.2d at 274.

**B. The Outpatient Prospective Payment System Statutory Scheme**

Plaintiffs argue that if CMS wants to reduce the payment rate for a particular OPD service, it must change the relative payment weights and adjustments through the annual review process, *see* 42 U.S.C. § 1395*l*(t)(9)(A), in a budget neutral manner, *see id.* § 1395*l*(t)(9)(B). Alternatively, if CMS wants to reduce Medicare costs by addressing "unnecessary increases in the volume of services," it must first develop a method to do so, *id.* § 1395*l*(t)(2)(F), which it may then implement across-the-board by adjusting the conversion factor, *see id.*

§ 1395*l*(t)(9)(C). This statutory scheme, Plaintiffs argue, is intended to prevent exactly what happened here: a selective cut to Medicare funding which targets only certain services and providers.

The government responds that CMS has authority to "develop a method for controlling unnecessary increases" in volume under paragraph (t)(2)(F) and that this authority is independent of its authority under paragraph (t)(9)(C) to adjust the conversion factor. It argues that these two actions are different and independent cost-control tools in its regulatory belt. Further, the government argues that CMS may develop a "method" to set payment rates for a particular service which is causing an "unnecessary" increase in cost (and volume) without regard to budget neutrality, because there is no logical reason Congress would want CMS to penalize all outpatient departments—by reducing rates for all OPD services—for the spike in volume (as measured by total expenditures) if only one such service caused the spike.

The government emphasizes that "method" is not explicitly defined in the statute and argues that its approach satisfies generic definitions of the term. *See, e.g.*, *Method*, Black's Law Dictionary (11th ed. 2019) ("A mode of organizing, operating, or performing something, esp. to achieve a goal."). But "reasonable statutory interpretation must account for both 'the specific context in which . . . language is used' and 'the broader context of the statute as a whole.'" *Util. Air Regulatory Grp.*, 573 U.S. at 321 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). "A statutory 'provision that may seem ambiguous in isolation is often clarified by the remainder of the statutory scheme . . . because only one of the permissible meanings produces a substantive effect that is compatible with the rest of the law.'" *Id.* (quoting *United Sav. Ass'n of Tex. v. Timbers of Inwood Forest Assocs., Ltd.*, 484 U.S. 365, 371 (1988)); *see also King v. Burwell*, 135 S. Ct. 2480, 2483 (2015) ("[O]ftentimes the meaning—or ambiguity—of

certain words or phrases may only become evident when placed in context."). As such, the Court must "read the words 'in their context and with a view to their place in the overall statutory scheme.'" *King*, 135 S. Ct. at 2483 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000)); *see also Util. Air Regulatory Grp.*, 573 U.S. at 320. That context does not make clear what a "method" is, but it does make clear what a "method" is *not*: it is not a price-setting tool, and the government's effort to wield it in such a manner is manifestly inconsistent with the statutory scheme. There are two reasons.

*First*, Congress established an elaborate statutory scheme which spelled out each step for determining the amount of payment for OPD services under the Outpatient Prospective Payment System. As detailed in 42 U.S.C. § 1395*l*(t)(4), titled "Medicare payment amount," the amount paid "is determined" by: the fee schedule amount "computed under paragraph (3)(D)" for the OPD service's Ambulatory Payment Classification, adjusted for wages and other factors "as computed under paragraphs (2)(D) and (2)(E)," *see* 42 U.S.C. § 1395*l*(t)(4)(A); less applicable deductibles under § 1395*l*(b), *see id.* § 1395*l*(t)(4)(B); and modified by a "payment proportion," *see id.* § 1395*l*(t)(4)(C). The applicable deductible and "payment proportion" are fixed by statute and are not relevant to this case, but the Ambulatory Payment Classification fee schedule amount is. That amount is the product of the conversion factor "computed under subparagraph [(3)(C)]" and the relative payment weight for the Ambulatory Payment Classification "determined under paragraph (2)(C)." *See id.* § 1395*l*(t)(3)(D). The base ingredients of an Outpatient Prospective Payment System payment over which CMS has discretion are, therefore, the Ambulatory Payment Classification groups and relative payment weights; the conversion factor; and the wage adjustment and other adjustments.

The Court recounts these cross-referencing provisions—even the irrelevant ones—to make one thing clear: nowhere is a "method" developed under paragraph (t)(2)(F) referenced. CMS cannot shoehorn a "method" into the multi-faceted congressional payment scheme when Congress's clear directions lack any such reference. *See Util. Air Regulatory Grp.*, 573 U.S. at 328. ("We reaffirm the core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate."). As such, if CMS wishes to reduce Outpatient Prospective Payment System payments for E&M services, it must make budget-neutral adjustments to either that service's relative payment weight or to other adjustments under paragraph (t)(9)(A). Alternatively, CMS may update the conversion factor to apply across-the-board cuts under paragraph (t)(9)(C). But nothing in the adjustment or payment scheme permits service-specific, non-budget-neutral cuts.

CMS apparently understood this limitation when it considered other "methods" in the past. For example, when the Outpatient Prospective Payment System was first being developed in 1998, CMS evaluated three possible methods of volume control, all based on the Sustainable Growth Rate formula which was enacted by Congress to control the growth of "physician services" under, ironically, the Physician Fee Schedule, which is itself also a prospective payment system. *See* 63 Fed. Reg. at 47,586. Much like payment rates for OPD services under the Outpatient Prospective Payment System, payment rates for physician services are prospectively set through a combination of relative resource use, regional adjustments, and an across-the-board Physician Fee Schedule conversion factor. The Sustainable Growth Rate formula set overall target expenditure levels for physician services based on changes in enrollment, changes in physician fees, changes in the legal and regulatory landscape, and total economic growth, and then manipulated the Physician Fee Schedule conversion factor to achieve

that targeted level. Two of CMS' proposals in 1998 would have modified the Sustainable Growth Rate formula to also account for a measure of OPD service efficiency as well, while the third proposal would have developed a similar, independent formula for the Outpatient Prospective Payment System. All three proposals would have operated through updates to the relevant conversion factors under paragraph (t)(9)(C).[8] *Id.* at 47,586-87. None of these methods, based upon a conversion factor calculated using a Sustainable Growth Rate formula, was implemented. *See* Final Rule at 59,005.

Instead, CMS considered and implemented a different method of volume control known as "packaging," whereby "ancillary services associated with a significant procedure" are "packaged into a single payment for the procedure." 72 Fed. Reg. 66,580, 66,610 (Nov. 27, 2007); *see also* Final Rule at 58,854 ("Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging . . . has been a fundamental part of OPPS since its implementation in August 2000."). Packaging incentivizes providers "to furnish services in the most efficient way by enabling hospitals to manage their resources with maximum flexibility, thereby encouraging long-term cost containment." 72 Fed. Reg. at 66,611; *see also* 63 Fed. Reg. at 47,586 ("We believe that greater packaging of these services might provide volume control."); 79 Fed. Reg. 66,770, 66,798-99 (Nov. 10, 2014) (introducing conceptually similar "comprehensive APCs"). Unlike the proposed methods based on a Sustainable Growth Rate formula that were considered in 1998, packaging does not control

[8] Plaintiffs argue that here CMS acknowledged "possible legislative modification" would be necessary to implement any method other than adjustment to the conversion factor. *See* Mem. of P. & A. in Supp. of Pls.' Mot. for Summ. J. [Dkt. 14-1] at 15; *see also* 63 Fed. Reg. at 47,586. As noted in the text, all three "methods" proposed in 1998 would have adjusted the conversion factor. Possible legislative modification was discussed because, for two of the proposed methods, CMS did not itself have the authority to modify the Sustainable Growth Rate, which Congress implemented by statute. *See* 42 U.S.C. 1395w-4(f) (1999)).

volume by changing the conversion factor and thereby obviates the need to rely on paragraph (t)(9)(C), and packaging is implemented in a budget neutral manner. *See, e.g.*, 72 Fed. Reg. at 66,615 ("Because the OPPS is a budget neutral payment system[,] . . . the effects of the packaging changes we proposed resulted in changes to scaled weights and . . . to the proposed payments rates for all separately paid procedures."); *cf.* 42 U.S.C. § 1395*l*(t)(9)(A)-(B).

This history makes it clear that CMS can adopt volume-control methods under paragraph (t)(2)(F) which affect payment rates indirectly, even if those methods cannot affect them directly. Moreover, it demonstrates that the Court's interpretation does not render paragraph (t)(2)(F) mere surplusage, since some methods do not depend on manipulation of the conversion factor.

*Second*, Congress provided great detail in directing how CMS should develop and adjust relative payment weights. For example, Congress required that the initial relative payment weights for OPD services be rooted in verifiable data and cost reports. *Id.* § 1395*l*(t)(2)(C). Congress also required CMS to develop a wage adjustment attributable to geographic labor and labor-related costs, *id.* § 1395*l*(t)(2)(D); an outlier adjustment to reimburse hospitals for particularly expensive patients, *id.* § 1395*l*(t)(2)(E) and (t)(5) (detailing further the outlier adjustment); a transitional pass-through payment scheme for innovative medical devices, drugs, and biologicals, *id.* § 1395*l*(t)(2)(E) and (t)(6) (detailing further the pass-through adjustment); and catch-all "other adjustments as determined to be necessary to ensure equitable payments," *id.* § 1395*l*(t)(2)(E). This extraordinarily detailed scheme results in a relative payment system which ensures that payments for one service are rationally connected to the payments for another and satisfies specific policies considered by Congress. And so that this system retains its integrity, CMS is required to review annually the relative payment weights of

OPD services and their adjustments based on changes in cost data, medical practices and technology, and other relevant information. *See id*. § 1395*l*(t)(9)(A). Further, CMS is required to consult with "an expert outside advisory panel" to ensure the "clinical integrity of the groups and weights." *Id.*

Congress also required that adjustments to the Outpatient Prospective Payment System be made in a budget-neutral fashion (with specified exceptions). Congress itself set the first conversion factor so that the estimated expenditures for the first year of payments under the Outpatient Prospective Payment System would match estimated expenditures for the same year under the previous system. *Id.* § 1395*l*(t)(3)(C)(i). Congress further specified that the wage adjustment, outlier adjustment, pass-through adjustment, and the "other adjustments" all be budget neutral. *Id.* § 1395*l*(t)(2)(D)-(E). And Congress directed CMS to make any changes to the groups, their relative payment weights, or the adjustments resulting from its mandatory annual review in a budget-neutral fashion. *Id.* § 1395*l*(t)(9)(B).

Notwithstanding this granularity in the statute, CMS posits that in a single sentence Congress granted it parallel authority to set payment rates in its discretion that are neither relative nor budget neutral. *Cf. id.* § 1395*l*(t)(2)(F). But "Congress . . . does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001); *cf. Air Alliance Houston v. EPA*, 906 F.3d 1049, 1061 (D.C. Cir. 2018) ("[I]t is well established that an agency may not circumvent specific statutory limits on its actions by relying on separate, general rulemaking authority."). If CMS reads the statute correctly, its new-found authority would supersede Congress' carefully crafted relative payment system by severing the connection between a service's payment rate and its relative resource use. In the context of the

similarly-designed Physician Fee Schedule system, Congress expressly denounced this disconnect. *See* H.R. Rep. No. 105-149, at 1347-48 (1997) ("As a result, relative value units have become seriously distorted. This distortion violates the basic principle underlying the resource-based relative value scale (RBRVS), namely that each services [sic] should be paid the same amount regardless of the patient or service to which it is attached."). Further, the structure of the Outpatient Prospective Payment System makes clear that Congress intended to preserve "the clinical integrity of the groups and weights." 42 U.S.C. § 1395*l*(t)(9)(A). There is no reason to think that Congress with one hand granted CMS the authority to upend such a "basic principle" of the Outpatient Prospective Payment System while working with the other to preserve it.[9]

The government also argues that Congress knew how to require budget neutrality when it wanted to, and that its silence in the context of paragraph (t)(2)(F) is telling. Not only does this argument fail to address damage to the integrity of the relative payment system, but in the context of the Outpatient Prospective Payment System, the reverse is also true: for decisions within CMS' discretion that might affect overall expenditures, Congress made clear when budget neutrality was *not* required. *See id.* § 1395*l*(t)(7)(I) (exempting transitional payments from budget neutrality); *id.* § 1395*l*(t)(16)(D)(iii) (exempting special payments from budget neutrality); *id.* § 1395*l*(t)(20) (exempting the effects of certain incentives from budget neutrality); *cf. id.* § 1395*l*(t)(3)(C) (permitting negative conversion factors); *id.* § 1395*l*(t)(14)(H) (exempting specific expenditure increases from consideration under paragraph (t)(9)). As CMS

[9] CMS' interpretation would also swallow paragraph (t)(9)(C) in its entirety: why would the agency go through the annual hassle of updating the conversion factor if it could use paragraph (t)(2)(F) to decrease or increase payment rates for disfavored or favored services whenever desired?

has said, "the OPPS is a budget neutral payment system." 72 Fed. Reg. at 66,615. Given how pervasively the statute requires budget neutrality in the Outpatient Prospective Payment System, Congress clearly considered effects on total expenditures critical to that system. Yet Congress did not mention the budgetary impact of paragraph (t)(2)(F) at all. The Court concludes that no such reference was made because Congress did not intend CMS to use an untethered "method" to directly alter expenditures independent of other processes. To the contrary, Congress directed that any "methods" developed under paragraph (t)(2)(F) be implemented through other provisions of the statute.[10]

Finally, the government argues that there is no reason Congress would have wanted CMS to penalize all outpatient departments in order to control unnecessary increases in the volume of a single type of service. Of course, that is exactly what Congress did when it applied the Sustainable Growth Rate formula to the Physician Fee Schedule under the Balanced Budget Act of 1997—the same Act which created the Outpatient Prospective Payment System—to disastrous results. *See* Jim Hahn & Janemarie Mulvey, Congressional Research Service, Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System 8 (2012) ("There is a growing consensus among observers that the SGR system is fundamentally flawed and is creating instability in the Medicare program for providers and beneficiaries."); *id.* ("One commonly asserted criticism is that the SGR system treats all services and physicians equally . . . to the detriment of physicians who are 'unduly' penalized."). Congress recognized its error and

[10] Paragraph (t)(9)(C) explicitly provides that methods developed under paragraph (t)(2)(F) may result in adjustments to the conversion factor because subsection (t)(3), governing the conversion factor, does not already provide CMS such authority. *Cf.* 42 U.S.C. § 1395*l*(t)(9)(A) (requiring CMS to review and adjust groups and relative payments weights and adjustments for OPD services). Put another way, the provision is permissive, not mandatory, because CMS may choose to implement its methods through other means.

repealed the Sustainable Growth Rate formula, *see* Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87, and it has demonstrated that it retains for itself the authority to make these and similarly selective funding decisions in this highly complicated intersection of patient needs, medical care, and government funding through the relative payment weight system. *See, e.g.*, Bipartisan Budget Act § 603 (establishing different payment schemes for excepted and non-excepted PBDs). Here, Congress has developed a multi-factored, complicated annual process whereby CMS is to pre-set relative payments for OPD services. This annual process would be totally ignored and circumvented if CMS could unilaterally set OPD service-specific rates without regard to their relative position or budget neutrality.

For these reasons, the Court finds that the "method" developed by CMS to cut costs is impermissible and violates its obligations under the statute. While the intention of CMS is clear, it would acquire unilateral authority to pick and choose what to pay for OPD services, which clearly was not Congress' intention. The Court find that the Final Rule is *ultra vires*.[11]

**C. Remedies**

A brief note on remedies. Plaintiffs not only ask for *vacatur* of the Final Rule, but also for a court order requiring CMS to issue payments improperly withheld due to the Final Rule. Plaintiffs' request will be denied. "'Under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards.'" *Palisades Gen. Hosp. Inc. v. Leavitt*, 426 F.3d 400 (D.C. Cir. 2005) (quoting *Cnty. of L.A. v. Shalala*, 192 F.3d 1005, 1011 (D.C. Cir. 1999)). That said,

[11] Because the Court concludes that service-specific unilateral price setting by CMS is not a "method" within the meaning of the statute, the Court does not reach Plaintiffs' other arguments.

Outpatient Prospective Payment System reimbursements are complex and a third set of plaintiffs in another case challenging the same rule has raised the spectre of complications resulting from an order to vacate. *See* Opposition to Defendant's Motion to Stay Proceedings, *Sisters of Charity Hospital of Buffalo, New York v. Azar*, No. 19-1446 (RMC) (July 25, 2019) Dkt. 13. Other courts in this district have wrestled with the ripple effects of *vacatur* caused by Medicare budget neutrality provisions and interest payments. *See Am. Hosp. Ass'n*, 348 F. Supp. 3d at 85-86 (requiring further briefing on remedies related to OPPS adjustments); *Shands Jacksonville Med. Ctr., Inc. v. Azar*, 2019 WL 1228061, at *2 (D.D.C. Mar. 15, 2019) (addressing plaintiff-specific interest payments on improper reimbursement determinations); *see also Amgen*, 357 F.3d at 112 ("Other circuits have noted the havoc piecemeal review of OPPS payments could bring about."). The Final Rule is less than one year old and did not apply budget neutrality principles. These factors should lessen the burden on reconsideration. Nonetheless, the Court will require a joint status report to determine if additional briefing is appropriate.

## IV. CONCLUSION

CMS believes it is paying millions of taxpayer dollars for patient services in hospital outpatient departments that could be provided at less expense in physician offices. CMS may be correct. But CMS was not authorized to ignore the statutory process for setting payment rates in the Outpatient Prospective Payment System and to lower payments only for certain services performed by certain providers. Plaintiffs' Motion for Summary Judgment, Dkt. 14, will be granted. The government's Cross-Motion for Summary Judgment, Dkt. 20, will be denied. The Court will vacate the applicable portions of the Final Rule and remand the matter for further proceedings consistent with this Memorandum Opinion. The parties will be required to submit a joint status report by October 1, 2019, to determine if additional briefing on remedies

is required, along with the CMS estimate as to the duration of further proceedings. A memorializing Order accompanies this Memorandum Opinion.

Date: September 17, 2019

ROSEMARY M. COLLYER
United States District Judge